

**HeartWare**

HEARTWARE LIMITED  
ACN 111 970 257



# PROSPECTUS

An underwritten offer of up to approximately 60 million fully paid ordinary shares at an issue price of \$0.50 per share. The number of shares to be offered pursuant to the offer is indicative only and the number of shares offered may vary. The Company is also offering in a separate US Private Placement up to approximately 10 million fully paid ordinary shares at an issue price of \$0.50 per share. The underwritten Offer and the US Private Placement is to raise up to approximately \$35 million.

Corporate Advisor to the Offer  
Inteq Limited ABN 16 055 971 232

Broker & Underwriter  
Emerging Growth Capital ABN 16 093 677 180



**INTEQ LIMITED**

Investment and Advisory House



Investment in the Shares of HeartWare Limited should be considered speculative.

## Important Notice

### *Restrictions on US Ownership under US Securities Laws*

The Shares offered under this Prospectus have not been registered under the US Securities Act of 1933, as amended ("US Securities Act"). The Shares may not be offered, sold or delivered in the United States or for the account or benefit of, any US person (as defined in section 12.12 of this Prospectus), unless the Shares have been registered under the US Securities Act or an exemption from the registration requirements of the US Securities Act is available. Accordingly, neither this Prospectus nor the application form may be sent to US persons or otherwise distributed in the United States. Hedging transactions in the Shares may not be conducted unless in compliance with the US Securities Act.

### *Important Notice*

This Prospectus is dated 17 December 2004 and a copy of this Prospectus was lodged with the Australian Securities and Investments Commission ("ASIC") on that date. Neither ASIC nor the Australian Stock Exchange ("ASX") take any responsibility for the contents of this Prospectus.

No Shares will be allotted or issued on the basis of this Prospectus later than 13 months after the date of this Prospectus. The Company will apply for admission to the official list of ASX and quotation of the Company's Shares within seven days after the date of this Prospectus.

This Prospectus is important and should be read in its entirety prior to making an investment decision. If you do not fully understand this Prospectus or are in doubt as to how to deal with it, you should consult your professional adviser. There are risks associated with an investment in the Company and the Shares offered under this Prospectus must be regarded as a speculative investment. Some of the risk factors that should be considered are set out in **Section 11**.

The distribution of this Prospectus in jurisdictions outside Australia may be restricted by law and persons who come into possession of this Prospectus should seek advice and observe any such restrictions. Any failure to comply with such restrictions may constitute a violation of applicable securities law. This Prospectus does not constitute an offer in any place which, or to any person to whom, it would not be lawful to make an offer.

### *Disclaimer*

No person is authorised to give any information or make any representation in connection with the Offer that is not contained in the Prospectus. Any information or representation not contained in this Prospectus may not be relied on as having been authorised by the Company in connection with the Offer.

### *Exposure period*

This Prospectus is subject to an Exposure Period of seven days from the date of lodgement with ASIC. This period may be extended by ASIC for a further period of up to seven days. The purpose of the Exposure Period is to enable this Prospectus to be examined by market participants prior to the raising of funds.

This Prospectus will be made generally available to Australian residents during the Exposure Period by being posted on the Company's website at [www.heartwareinc.com](http://www.heartwareinc.com). A paper copy of the Prospectus will be available for Australian residents free of charge by contacting **Emerging Growth Capital Pty Limited** on (02) 9222 1991.

If this Prospectus is found to be deficient, any Applications may need to be dealt with in accordance with s 724 of the Corporations Act. Applications received under this Prospectus during the Exposure Period will not be processed until after the expiry of the Exposure Period. No preference will be conferred on Applications received during the Exposure Period.

### *Electronic prospectus*

This Prospectus may be viewed online at the Company's website

[www.heartwareinc.com](http://www.heartwareinc.com). Any person accessing the electronic version of this Prospectus for the purposes of making an investment in the Company must be an Australian resident and must access the Prospectus from within Australia. Persons who access the electronic version of this Prospectus should ensure that they download and read the entire Prospectus. If unsure about the completeness of the Prospectus received electronically, or a print out of it, you should contact the Company.

Applications may only be made on a printed copy of the Application Form attached to or accompanying this Prospectus. The Corporations Act prohibits any person from passing the Application Form on to another person unless it is attached to a hard copy of the Prospectus or the complete and unaltered electronic version of the Prospectus.

### *US private placement*

Concurrently with the offer under this Prospectus, the Company will be making a separate offer of Shares in the US to certain US persons, as discussed in more detail in **Section 12** of this Prospectus, in reliance on an exemption from registration with Regulation D under the US Securities Act ("US Private Placement"). The Shares to be issued under the offer pursuant to this Prospectus are part of a separate transaction in reliance on an exemption from registration with Regulation S under the US Securities Act.

### *Privacy*

If you apply for Shares under this Prospectus, you will provide personal information to the Company (and its share registry). If you do not wish to provide this information, the Company may not be able to process your application. Personal information is collected and used in order to process your application, comply with the Company's obligations under Part 2C of the Corporations Act and to administer your investment.

In processing and administering your investment, the Company may disclose your personal information to related bodies corporate, the Company's agents, contractors or third party advisers that provide financial, administrative or other services in connection with the Company's business. Furthermore, the Corporations Act requires the Company to allow anyone to inspect its public registers, including the share registry, which may (if required by law) contain your personal information.

Under the Privacy Act 1988 (Cth), you may request access to your personal information that is held by, or on behalf of, the Company. You can do this by contacting the Company, or its share registry, details of which are set out elsewhere in this Prospectus.

### *Definitions and abbreviations*

This Prospectus contains a number of terms that have a meaning. Details of the definitions and abbreviations used are set out in **Section 14** of this Prospectus.

### *Financial amounts*

The financial amounts referred to in this Prospectus are expressed in Australian dollars unless stated otherwise.

### *AEDT*

All references to time in this Prospectus refer to Australian Eastern Daylight Time unless stated otherwise.

### *Consents*

This Prospectus contains certain information provided by the Company and its directors concerning the business, financial position and future intentions of the Company. To the extent that the Prospectus includes a statement by the Company or its directors or includes a statement based on any statements of, or information provided by, the Company and its directors, the Company and each of its directors consents to each such statement being included in the Prospectus in the form and context in which it is included and has not withdrawn that consent at any time prior to lodgement of the Prospectus with ASIC.

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Application Form

## Key Information

This Prospectus provides the opportunity to participate in the offer of Shares in HeartWare Limited.

### KEY OFFER STATISTICS

|                       |        |
|-----------------------|--------|
| Offer Price per Share | \$0.50 |
|-----------------------|--------|

#### At the Lower Target Subscription:

|  |              |
|--|--------------|
| Shares offered under this Prospectus <sup>1</sup>      | 60,000,000   |
| Amount to be raised under this Prospectus <sup>2</sup> | \$30,000,000 |
| Total Shares on issue following the Offer              | 148,002,000  |
| Capitalisation at Offer Price                          | \$74,001,000 |

#### At the Upper Target Subscription:

|  |              |
|--|--------------|
| Shares offered under this Prospectus <sup>1</sup>      | 70,000,000   |
| Amount to be raised under this Prospectus <sup>2</sup> | \$35,000,000 |
| Total Shares on issue following the Offer              | 158,002,000  |
| Capitalisation at Offer Price                          | \$79,001,000 |

|  |            |
|--|------------|
| <i>Options on Issue at Upper Target Subscription – see Financial Section for details</i> | 17,803,761 |
|--|------------|

<sup>1</sup> This includes 10.0 million Shares to be acquired by Apple Tree Partners and other “accredited investors” under the US Private Placement as described in **Section 12** of this Prospectus.

<sup>2</sup> This includes \$5.0 million to be raised under the US Private Placement as described in **Section 12** of this Prospectus.

The number of Shares to be offered pursuant to the offer is indicative only and the number of Shares offered may vary.

These amounts to be raised are also indicative only. The Company intends to raise not more than the Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date. The Company reserves the right to allot less than 60 million Shares or more than 70 million Shares in order to raise approximately, but not more than, the Australian dollar equivalent of US\$24,950,000 calculated as at the allotment date.

For more details see **Section 1.1**.

### KEY DATES

|   |                             |
|---|-----------------------------|
| Opening Date                                    | Wednesday, 29 December 2004 |
| Closing Date                                    | Wednesday, 19 January 2005  |
| Issue and allotment of Shares                   | Monday, 24 January 2005     |
| Dispatch of transaction confirmation statements | Monday, 24 January 2005     |
| ASX Listing                                     | Monday, 31 January 2005     |

These dates are indicative only. The Company, in consultation with the Underwriter, reserves the right to vary any of these dates without notice. Applicants are encouraged to apply as soon as possible after the Offer opens as the Offer may close earlier than the date specified.

### HOW TO APPLY FOR SHARES

An application for Shares under the Offer can only be made by completing the Application Form accompanying this Prospectus. Detailed instructions on completing an Application Form are set out on the reverse of that form.

## Letter from the Chairman

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Dear Investor,

On behalf of the Board of Directors, it is with great pleasure that I invite you to become a shareholder of HeartWare Limited (the “Company” or “HeartWare”). The Company intends to commercialise its range of circulatory assist devices or heart pumps, used for the treatment of congestive heart failure.

Heart failure is one of the leading causes of death in the developed world, affecting over 10 million people globally. In the United States alone, nearly five million patients suffer from heart failure and 550,000 new cases are diagnosed each year. According to the Australasian Society of Cardiac and Thoracic Surgeons, “In 2000, we estimate that around 325,000 Australians (58% male) had symptomatic HF [sic. heart failure]... Australia is in the midst of a HF epidemic that continues to grow... at a cost of more than \$1 billion”. The five-year survival rate for heart failure is approximately 50% whereas the one year survival of those with severe heart failure is 25%.

HeartWare believes its family of circulatory assist devices has the potential to substantially reduce morbidity and mortality associated with heart failure. This means that HeartWare has an opportunity to establish itself in the heart failure market, which represents one of the largest medical needs in developed economies.

HeartWare believes that its technology enables the creation of full output circulatory assist devices that are smaller and more efficient than those of competitors. Small size is a key competitive advantage which HeartWare believes will improve surgical implantation, expand the range of patients and enhance the patients’ quality of life. HeartWare believes that the HVAD is the only device of its type that can be implemented in the space directly surrounding the heart, rather than in the abdomen, leading to significant advantages. HeartWare plans to enter human clinical trials for the HVAD during the fourth quarter of 2005 with the first implant in early 2006.

HeartWare is developing further miniaturised products with its technology and has commenced development of its second product, the ‘Miniaturised VAD’ or ‘MVAD’, which has been designed to achieve the same circulatory performance as the HVAD but is approximately one tenth the size. HeartWare believes that the MVAD could open the market for circulatory assist devices to less sick heart failure patients, significantly increasing the available market.

The Company is offering, under this Prospectus and in a separate US private placement, approximately 60 to 70 million new fully paid ordinary Shares at an offer price of \$0.50 per share to raise approximately, but not more than, an aggregate Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date. The funds raised under this Offer will be used for the commercialisation and continued development of the Company’s technology and general corporate purposes. It is expected that the funds raised will enable HeartWare to commence HVAD clinical trials in Australia and Europe, to initiate HVAD trials in the US, and to continue research and development on the MVAD.

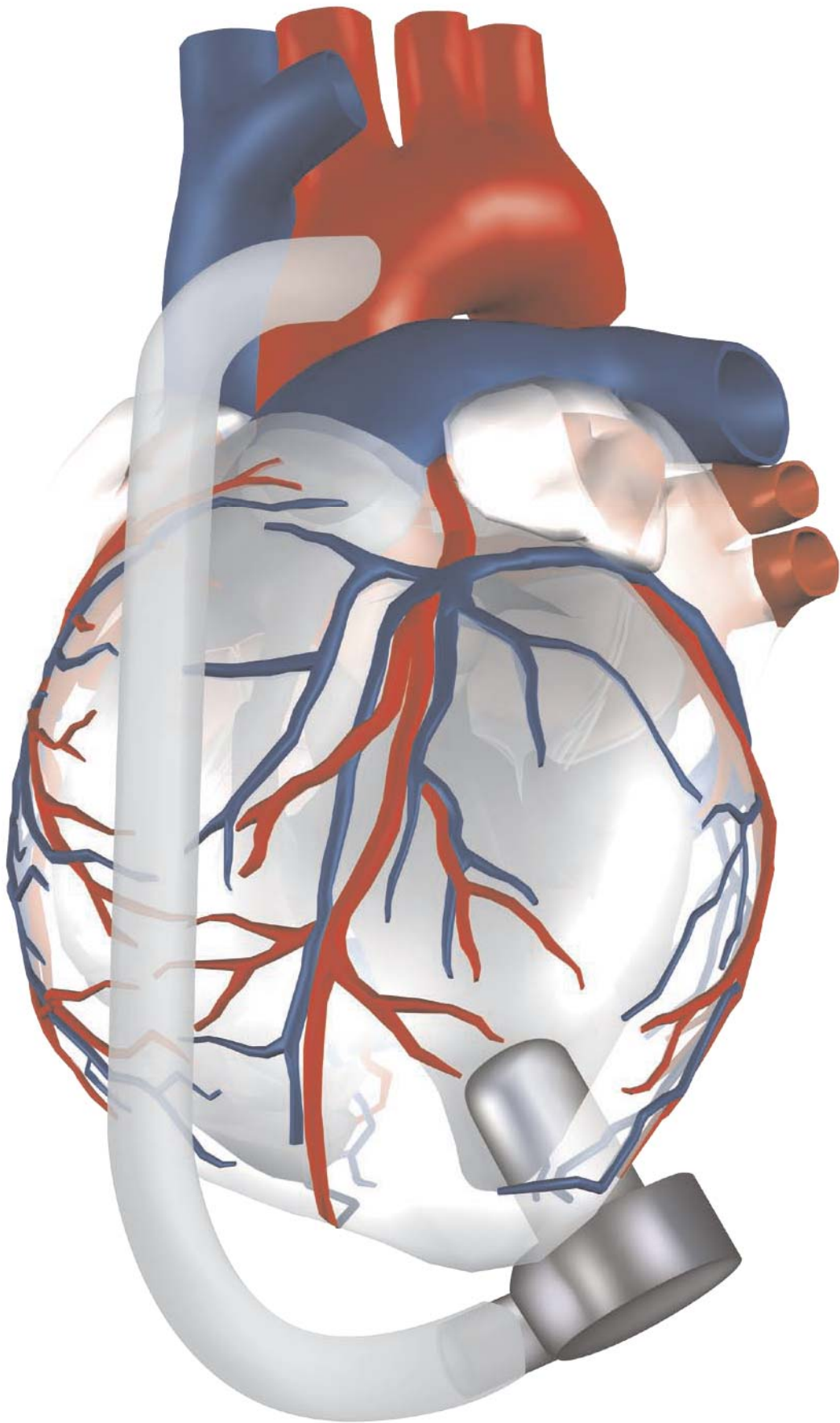
I am very pleased that, as an indication of their continued support for the Company, Apple Tree Partners I, L.P. and its affiliates have committed to subscribe for a further \$5 million of Shares under the US Private Placement being conducted concurrently with the Offer. Apple Tree Partners I, L.P. is the largest shareholder in the Company.

Though investment in the Company involves a number of risks and must be considered speculative, I believe it represents an excellent opportunity to participate in the building of what can become a significant, internationally competitive business. On behalf of my fellow Directors, I commend this investment opportunity to you and look forward to welcoming you as a shareholder in the Company.

Yours faithfully,  
**Robert Thomas**  
Chairman



*This Prospectus contains detailed information about the Offer and the Company. This Prospectus and, in particular, Section 11 (Risk Factors) should be read in its entirety before making your investment decision. This investment should be considered speculative.*





# Investment Highlights

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## Business Summary

HeartWare is developing a range of implantable circulatory assist devices, or 'heart pumps', aimed at treating patients with congestive heart failure.

Heart failure is one of the leading causes of death in the developed world, affecting over 10 million people globally. Despite advances in treatment, the five year survival rate for heart failure is approximately 50% whereas the one year survival rate of those with severe heart failure is 25%.

HeartWare's proprietary technology has been in development for nearly ten years, with approximately \$46 million (US\$32 million) invested and committed to date. The Company's technology platform enables the creation of devices that are believed to be considerably smaller than others of which the Company is aware, that are under development. This ability to "miniaturise" gives rise to significant potential advantages, in terms both of improved patient outcome and the ability to treat a far wider range of patients and conditions. HeartWare's most developed product, the HVAD, has undergone extensive animal testing and is expected to commence human clinical trials in late 2005.

HeartWare's technology development and manufacturing facility is in Miramar, Florida. This US operations centre will also provide an established base from which to access the US market. HeartWare's corporate headquarters will be in Sydney, where the Chief Executive Officer and the majority of the Company's directors are, or will be based. The Australian headquarters will manage financial and investor relations functions, co ordinate the Australian clinical trial programme and eventually service the Asia Pacific markets.

The Company's management team and Board have extensive experience in the development and commercialisation of medical products. These skills are supplemented by the expertise of HeartWare's Advisory Board, which includes some of the world's leading cardiac specialists.

HeartWare is seeking to raise, under this Prospectus and in a separate US private placement, the Australian dollar equivalent of US\$24,950,000. As the funds raised will predominantly be spent in the United States, the Company will allot sufficient Shares to raise this amount in US dollars. Funds will be applied to complete preclinical trials, conduct human clinical trials and submit regulatory applications for the Company's first product, the HVAD. Sales of the HVAD are anticipated in mid 2007. Funds will also be used for the further development of HeartWare's next generation products, the MVAD and the PedVAD.

...believed to be the smallest, most reliably designed and most durable full output circulatory assist device



## Products and Technology

HeartWare’s technology is protected by a portfolio of 14 US and 10 international patents. Its device family includes three products, the HVAD, MVAD and PedVAD, which are at varying stages of development.

The HVAD, HeartWare’s initial product has been designed to be the smallest, most reliable and most durable full output circulatory assist device developed to date. The Company believes the HVAD to be the only full output circulatory assist device that can be implanted in the space directly surrounding the heart (pericardial space). Competing devices are generally implanted in the abdomen, often leading to increased operating time and procedure-related complications. The HVAD is designed to support one or both sides of the heart allowing its use in a wide range of heart failure patients. HeartWare expects the HVAD to enter clinical trials in late 2005.

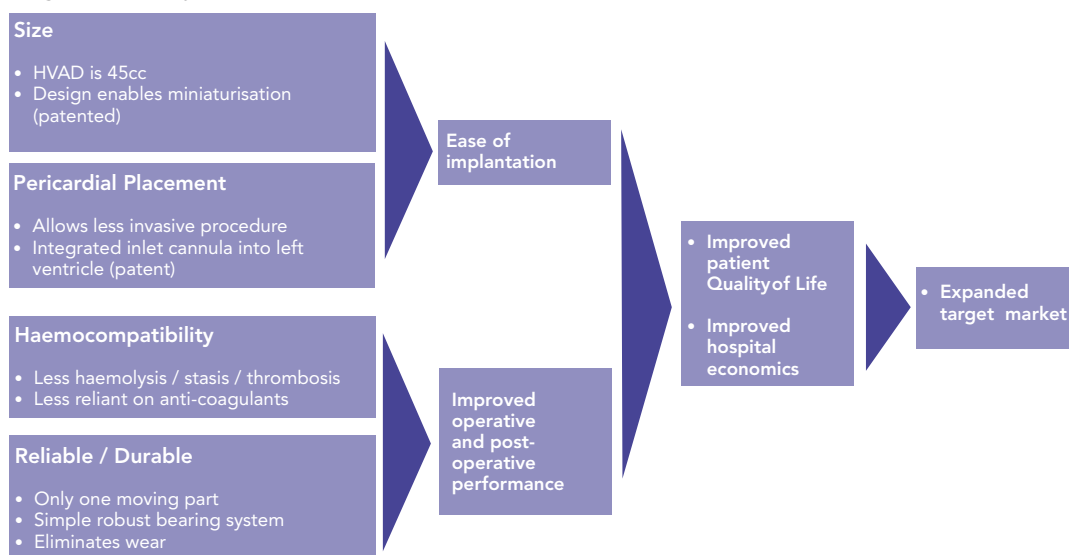
HeartWare’s second product, the MVAD, is at the prototype stage. With the MVAD the Company expects to achieve similar circulatory performance characteristics to the HVAD, but in a device approximately one tenth the HVAD’s size. The MVAD is designed to be implanted via catheterisation and minimally invasive surgery. This much less invasive surgery is expected to facilitate the use of the MVAD to treat a wider spectrum of heart failure patients than is possible with current technology.

The MVAD serves as a basis for HeartWare’s third product, the Paediatric Ventricular Assist Device or PedVAD, aimed at addressing the medical needs of children with advanced heart failure. The Company expects to develop the PedVAD, in part, with grant funding from the Artificial Heart Fund (UK).

## Competitive Advantages

HeartWare’s HVAD is 45cc in volume, believed to be approximately one-third the size of most potential full output competitive products. This size is expected to give rise to a faster, more straightforward implantation procedure than that required for competing devices. The relative simplicity of the procedure is expected to facilitate the broader use of the HVAD in general heart surgery hospitals. Larger devices, requiring more complex implantation procedures, are usually implanted in heart transplantation centres, the number of which is smaller than the number of general heart surgery hospitals.

Those device characteristics which HeartWare believes are its key competitive advantages are shown diagrammatically below:





## Market

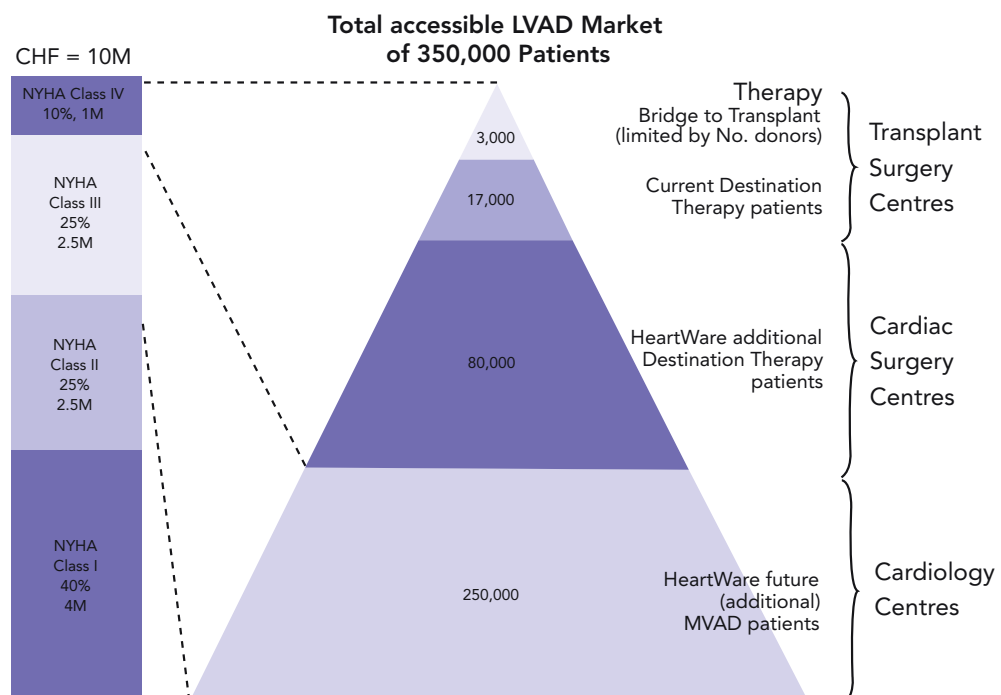
Worldwide, the Company estimates that approximately 100,000 end stage heart failure patients could benefit from its HVAD. These patients fall into two categories, 'destination therapy' and 'bridge to transplant', with 'destination therapy' accounting for the vast majority of the total. HeartWare's principal market and regulatory emphasis for the HVAD is destination therapy, however obtaining regulatory approval for bridge to transplant is considered important in both the US and the EU.

- Destination therapy refers to the permanent or quasi permanent use of a circulatory assist device in patients suffering from end-stage heart failure. Assuming device pricing of \$100,000 (US\$70,000) the Company estimates the total available destination therapy market to exceed \$10 billion (US\$7 billion).
- Bridge to transplant refers to the temporary use of a circulatory assist device in end-stage heart failure patients awaiting heart transplant. There are approximately 3,000 heart transplant procedures conducted each year. As not all transplant list patients will require a device, HeartWare estimates the total available 'bridge to transplant' market to be approximately \$100 million.

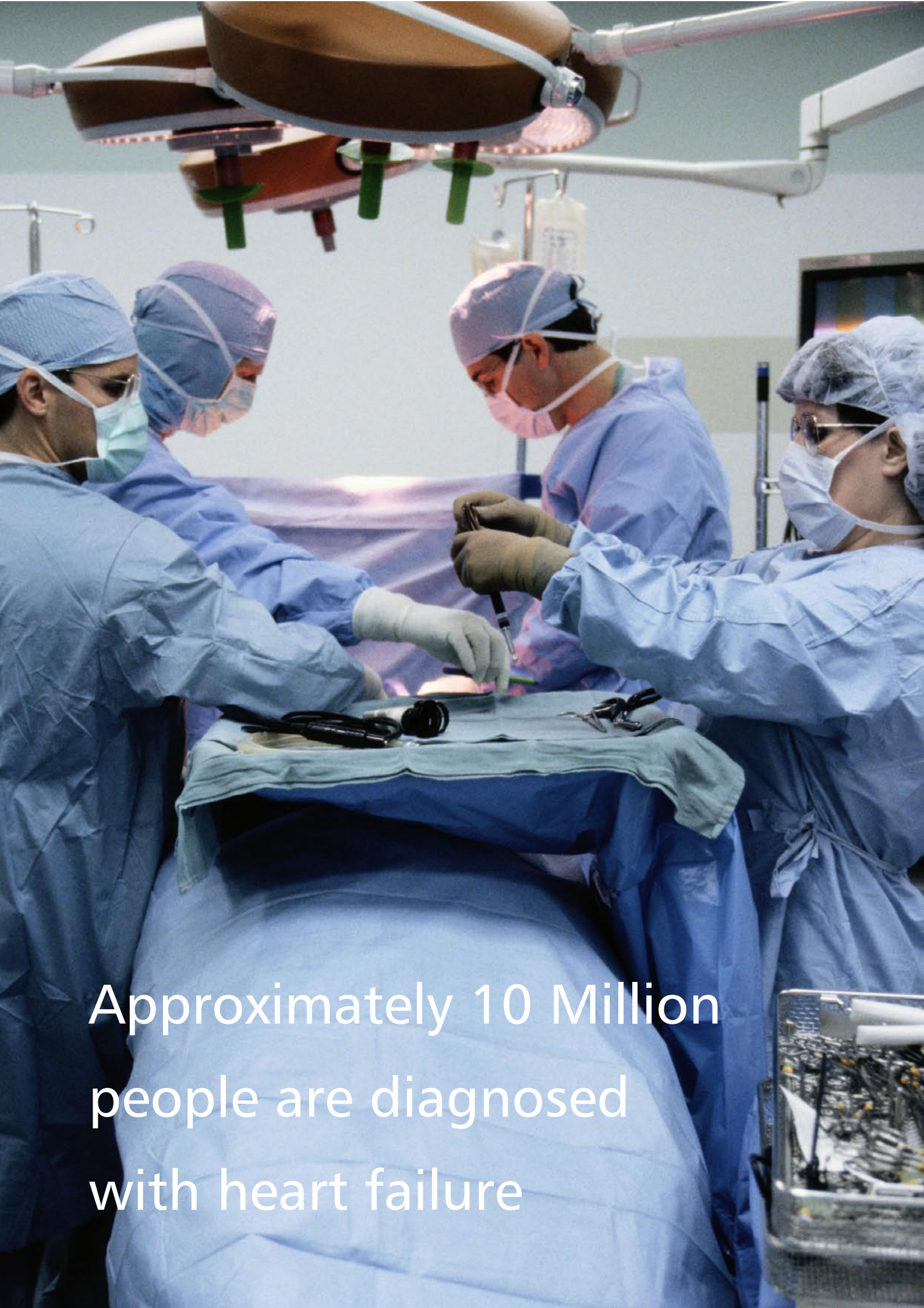
Because the HVAD is designed for ease of implantation, HeartWare expects that general cardiac surgery hospitals (in addition to the relatively small number of cardiac transplant centres) will be able to conduct the procedure, thereby providing access to the broadest possible end-stage heart failure market.

The MVAD is expected to broaden HeartWare's target market to include NYHA Class III patients, estimated to represent a further 250,000 patients. HeartWare's estimated HVAD and MVAD markets are shown below:

*The Congestive Heart Failure (CHF) market is estimated to be 10 million people globally*



- Note:**
1. New York Heart Association ("NYHA") is the scale used to classify degrees of heart failure
  2. The worldwide ratio of Cardiac Centres to Transplant Centres is assumed to be approximately 10:1
  3. HeartWare assumes 10% of Class III and IV as the target market



Approximately 10 Million  
people are diagnosed  
with heart failure

## Commercialisation Plans

HeartWare’s commercial focus is the rapid advancement of its lead product, the HVAD, to clinical trials and regulatory approval. The clinical trials are expected to take place initially in Australia and the EU, with the US trials to follow as soon as possible thereafter. Anticipated clinical milestones are as follows:

| Year | Quarter | Milestone  |
|------|---------|--|
| 2005 | Fourth  | Complete all final verification and approvals for first human implants   |
| 2006 | First   | First human implant, in a combined Australian/EU multi centre trial: <ul style="list-style-type: none"> <li>• Australian trials for destination therapy and bridge to transplant, at two major centres – discussions underway with investigators at Royal Perth Hospital and St Vincent’s Sydney</li> <li>• EU trials for destination therapy and bridge to transplant, at up to five major centres - discussions underway with investigators at the University of Vienna and the John Radcliffe Hospital in Oxford</li> </ul> |
|      |         | IDE Approval from the FDA to commence US human trials  |
|      |         | US bridge to transplant trials commence in up to 15 centres (implants expected to be reimbursed)   |
|      | Third   | US destination therapy trials commence in up to 30 centres (implants expected to be reimbursed)  |
|      | Fourth  | Complete implants for Australian/EU multi centre trial   |
| 2007 | Third   | CE Mark and Australian TGA approval<br>EU and Australian commercial sales commence   |
| 2008 | Fourth  | FDA approval for bridge to transplant patients – US sales commence for bridge to transplant  |
| 2009 | Fourth  | FDA approval for destination therapy – US sales commence   |

In parallel, HeartWare intends to continue the development of its MVAD and PedVAD devices.

## Experienced Board and Management

HeartWare is chaired by Mr Rob Thomas, the former Chairman of Citigroup Australia’s Corporate and Investment Bank. Other directors include Seth Harrison MD, Managing Partner of Apple Tree Partners I,L.P. (“**Apple Tree Partners**”), a US venture capital firm, Dr Christine Bennett, Chief Executive Officer of Research Australia Limited, and Dr Denis Wade AM, formerly Chairman of Johnson & Johnson Research Pty Limited.

HeartWare’s Managing Director and CEO is Mr Stuart McConchie. Mr McConchie has approximately 25 years of medical device company experience including over 10 years in the heart failure device industry.

The Board and Management are supported by a team of experienced engineers and highly qualified clinical and regulatory affairs personnel and advisors.

## Advisory Board

The Company's Advisory Board comprises medical practitioners in cardiothoracic surgery, ventricular device implantation, biomedical engineering and cardiology. Members of the Advisory Board include:

- **O. Howard 'Bud' Frazier MD** (Chief of Transplant Services, Texas Heart Institute): who has implanted almost 300 left ventricular assist devices. Dr Frazier is Chairman of the Advisory Board.
- **Steven Boyce MD** (Director of Heart Transplantation Washington Hospital Centre): who has been involved with the development of HeartWare's devices since 1997.
- **Leslie Miller MD** (Director Cardiovascular Division, University of Minnesota): who is Director of the Heart Failure/Heart Transplant Program at the University of Minnesota in Minneapolis and has been involved in the study of congestive heart failure.
- **Laman Gray Jr. MD** (Director of Thoracic and Cardiovascular Surgery, University of Louisville): who is experienced in the fields of cardiac surgery and development of artificial hearts and circulatory support systems.
- **Mr Stephen Westaby** (Cardiothoracic surgeon, John Radcliffe Hospital): who conducts over 500 cardiac operations annually and is a circulatory assist device pioneer having implanted the longest surviving LVAD patient.
- **Dr Georg Wieselthaler** (Clinical Director of Mechanical Circulatory Support, Vienna General Hospital): who is the primary surgeon implanting the various VAD systems and supervising patient care at the University of Vienna with a background in biomedical engineering.

## Australian Opportunity

HeartWare will base its corporate headquarters in Sydney in order to:

- Provide a local base from which to conduct HVAD clinical trials for 'destination therapy'. Australian regulatory and clinical resources relating to circulatory assist devices are comparable to those available in the US and Europe.
- Take advantage of what HeartWare believes to be an expedited clinical trial process in Australia and Europe as compared to the US.
- Provide a base from which to launch its products into the Asia Pacific markets.

HeartWare's Australian presence is expected to facilitate access to leading clinical resources and help expedite the clinical trial process, while the Company's established US base should be advantageous in managing the US market and regulatory requirements.

## Summary of Restrictions on US Ownership under US Securities Laws

The Shares offered under this Prospectus have not been registered under the US Securities Act of 1933, as amended. The Shares may not be offered, sold or delivered in the United States or for the account or benefit of any US person (as defined in **Section 12.12** of this Prospectus), unless the Shares have been registered under the US Securities Act or an exemption from the registration requirements of the US Securities Act is available. Accordingly, neither this Prospectus nor the application form may be sent to US persons or otherwise distributed in the United States.

The logo consists of a series of grey dots of varying sizes arranged in a semi-circular arc, with the text "Investment Highlights" in a grey sans-serif font to its right.

# Investment Highlights

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US persons are prohibited from acquiring any Shares. In order to ensure that US persons do not purchase any Shares, a number of procedures governing the trading and clearing of the Shares will be implemented, including the application to the Shares of the status of Foreign Ownership Restriction (FOR) securities under the ASTC Settlement Rules and the addition of the notation "FORUS" to the Shares' description on ASX trading screens and elsewhere. The FORUS notation will inform the market of the prohibition on US persons owning Shares.

For more information about restrictions on US ownership under US securities laws, please see **Section 12.12** of this Prospectus.

*The Investment Highlights set out above are a summary only. This Prospectus and in particular **Section 11 (Risk Factors)** should be read in its entirety before an Application is made.*

*This investment should be considered speculative.*



# 1 Details of the Offer

## 1.1 The Offer

The Company is offering investors, under this Prospectus (“Offer”) and in a separate US private placement discussed further in **Section 12.12** of this Prospectus (“US Private Placement”), the opportunity to subscribe for Shares to raise approximately, but not more than, an aggregate Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date.

At an exchange rate of A\$1.00 = US\$0.8317 this equates to 60 million Shares at a price of \$0.50 per Share to raise \$30 million (“Lower Target Subscription”) and at an exchange rate of A\$1.00 = US\$0.7129 this equates to 70 million Shares at a price of \$0.50 per Share to raise \$35 million (“Upper Target Subscription”).

The Company reserves the right to allot less than 60 million Shares or more than 70 million Shares in order to raise not more than the Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date.

All Shares being offered under this Prospectus and the US Private Placement will on issue rank equally in all respects with existing issued Shares.

The Offer is likely to be characterised as a proposal to establish a “new business” for the purpose of the Australian Foreign Acquisitions and Takeovers Act 1975 (Cth) (“FATA”). As a result, the Offer is subject to Foreign Investment Review Board (“FIRB”) approval unless such approval is no longer required by reason of a change in the law. The scheduled entry into force of the Australia-United States Free Trade Agreement on 1 January 2005, with the consequent amendment of FATA on that date, will remove the threshold for proposals to establish a “new business”, such that FIRB approval of the Offer would no longer be required.

**As discussed further in Section 12.12 of this Prospectus, the Offer has not been and will not be registered under the US Securities Act, or any securities laws of any state or other jurisdiction in the US and under the Offer, Shares may not be offered or sold in the US or to, or for the account or benefit of, any US person.**

## 1.2 Broker and Underwriter to the Offer

The Offer has been underwritten by Emerging Growth Capital Pty Limited (“eG Capital” or the “Underwriter”). The key provisions of the Underwriting Agreement and the circumstances under which the Underwriter may terminate its obligations are set out in **Section 12.6**. Investors should note that none of the obligations of the Company are guaranteed in any way by the Underwriter, nor does the Underwriter guarantee the capital value or performance of the Company.

## 1.3 Proceeds of the Issue

The amount raised under the Offer will be applied to the ongoing commercialisation and continued development of the Company’s technology, general corporate purposes and the expenses of the Offer. As the funds raised will predominantly be spent in the United States the proposed use of funds in US dollar terms will not vary between the Lower Target Subscription and the Upper Target Subscription. The table below sets out in Australian dollar terms the proposed Use of Funds based on both the Lower Target Subscription and the Upper Target Subscription.



# 1 Details of the Offer

| Use of Funds  | Lower Target Subscription <sup>1</sup> |               | Upper Target Subscription <sup>2</sup> |               |
|---|--|---------------|--|---------------|
|   | \$000's                                | \$000's       | \$000's                                | \$000's       |
| Commercialisation and further development of the HVAD |  |               |  |               |
| HVAD Product Development                              | 4,352                                  |               | 5,077                                  |               |
| HVAD Clinical Trials – Australia and EU               | 2,657                                  |               | 3,100                                  |               |
| HVAD Clinical Trials – US (through 2006)              | 1,403                                  |               | 1,637                                  |               |
|   |  | <b>8,412</b>  |  | <b>9,814</b>  |
| Development of next generation technology             |  |               |  |               |
| MVAD Product Development                              |  | <b>4,594</b>  |  | <b>5,360</b>  |
| Manufacturing Upgrade and Capital Expenditure         |  | <b>2,394</b>  |  | <b>2,793</b>  |
| Business Operations & Working Capital                 |  |               |  |               |
| Corporate & Compliance Costs                          | 2,882                                  |               | 2,894                                  |               |
| Sales & Marketing                                     | 532                                    |               | 620                                    |               |
| Operational Expenses and staff                        | 5,242                                  |               | 6,149                                  |               |
| General and Administration                            | 3,114                                  |               | 3,531                                  |               |
| Other   | 158                                    |               | 1,112                                  |               |
|   |  | <b>11,928</b> |  | <b>14,306</b> |
| Costs of this offer                                   |  | <b>2,672</b>  |  | <b>2,727</b>  |
| <b>Total</b>  |  | <b>30,000</b> |  | <b>35,000</b> |

<sup>1</sup> The Lower Target Subscription assumes an exchange rate of A\$1.00 = US\$0.8317.

<sup>2</sup> The Upper Target Subscription assumes an exchange rate of A\$1.00 = US\$0.7129.

Following completion of the Offer, the Directors believe that the Company will have sufficient working capital to conduct its business for at least the next 18 months.

## 1.4 Capital Structure

As at the date of this Prospectus the total issued capital of the Company is 2,000 ordinary Shares issued to Apple Tree Partners for a total of \$1,000.

The Shares to be issued by the Company under the Acquisition and the Offer, subject to their terms, are as follows:

| Number of Shares at the Lower Target Subscription: |                 |                        |                         |                    |                  |
|--|-----------------|------------------------|-------------------------|--------------------|------------------|
| Holder   | Opening Balance | Issued for Acquisition | Issued under this Offer | Final Total        | % of Final Total |
| Apple Tree Partners                                | 2,000           | 87,003,221             | -                       | 87,005,221         | 58.79            |
| Other HeartWare, Inc. holders                      | -               | 996,779                | -                       | 996,779            | 0.67             |
| New Investors under the Offer <sup>1</sup>         | -               | -                      | 60,000,000              | 60,000,000         | 40.54            |
| <b>Total</b>                                       | <b>2,000</b>    | <b>88,000,000</b>      | <b>60,000,000</b>       | <b>148,002,000</b> | <b>100.00%</b>   |



# 1 Details of the Offer

| Number of Shares at the Upper Target Subscription: |                 |                        |                         |                    |                  |
|--|-----------------|------------------------|-------------------------|--------------------|------------------|
| Holder   | Opening Balance | Issued for Acquisition | Issued under this Offer | Final Total        | % of Final Total |
| Apple Tree Partners                                | 2,000           | 87,003,221             | -                       | 87,005,221         | 55.07            |
| Other HeartWare, Inc. holders                      | -               | 996,779                | -                       | 996,779            | 0.63             |
| New Investors under the Offer <sup>1</sup>         | -               | -                      | 70,000,000              | 70,000,000         | 44.30            |
| <b>Total</b>                                       | <b>2,000</b>    | <b>88,000,000</b>      | <b>70,000,000</b>       | <b>158,002,000</b> | <b>100.00%</b>   |

<sup>1</sup>This includes 10.0 million Shares to be acquired by Apple Tree Partners and other “accredited investors” under the US Private Placement as described in **Section 12** of this Prospectus.

In addition, the Company has issued 20,412,421 options over Shares. Further detail in relation to the capital structure and these options is set out in **Section 12.5**.

The number of Shares to be offered pursuant to the Offer is indicative only and the number of Shares offered may vary. Similarly, the amounts to be raised are indicative only. For more details see **Section 1.1**.

## 1.5 Financial Prospects, Dividend Policy and Risk Factors

The Company is in a commercial development stage. Revenues, profits and cash flows for the Company are dependent on a number of factors, many of which are described in this Prospectus. In light of these factors the Directors consider that, at this stage of the Company’s development, they are unable to provide potential investors with reliable revenue, profit or cash flow projections or forecasts.

The primary focus of the Company is to commercialise and continue the development of its existing technology. During this phase, the Company is unlikely to pay a dividend. The ability of the Company to pay a dividend in the future and the timing of any dividend will be dependent on a number of factors including deriving sufficient cash flows from future operations and the level of future profits.

As the Company is in a development phase and has no present revenues or revenue contracts, an investment in the Company should be regarded as being speculative and involving a number of risks. Many of these risks are set out throughout this Prospectus and, in particular, in **Section 11**.

## 1.6 Offer Opening and Closing

The Offer Opens at 9am on Wednesday, 29 December 2004 (AEDT).

The Offer Closes at 5pm on Wednesday, 19 January 2005 (AEDT) (unless closed earlier).





# 1 Details of the Offer

## 1.7 How to apply for Shares

The offer comprises two components:

### *General Public Application*

Applications from the general public must be for at least 4,000 Shares (\$2,000) and thereafter in multiples of 1,000 Shares (\$500).

An application for Shares can only be made by completing and lodging an Application Form attached to or accompanying this Prospectus. The Application Form must be completed in accordance with the instructions on its reverse side.

The Application Form must be accompanied by the payment in Australian currency of \$0.50 per Share. **Cheques should be made payable to "HeartWare Limited – Subscription Account" and crossed "Not Negotiable"**. Cheques must be drawn on an Australian branch of an Australian bank.

No US persons (see **section 12.12** of this Prospectus) may apply for Shares under the Offer.

Completed Application Forms must be received by the Share Registry before 5.00 pm AEDT on Wednesday, 19 January 2005 at the following address:

**Registries Limited**  
**Level 2, 28 Margaret Street**  
**SYDNEY NSW 2000**  
**Telephone: (02) 9290 9600**

The Company, in conjunction with the Underwriter, reserves the right to vary the Closing Date and other dates without notice. Lodgement of an Application Form constitutes an irrevocable offer to acquire Shares on the terms set out in this Prospectus.

### *Broker Firm Application*

Applications from persons who receive a firm application of Shares from their broker must be for a minimum of 4,000 Shares (\$2,000) and thereafter in multiples of 1,000 Shares (\$500).

Application forms and payment must be made in accordance with the instructions from your relevant broker.

**DO NOT SEND BROKER FIRM APPLICATIONS TO THE REGISTRY.**

## 1.8 Acceptance of applications and allocation policy

An application for Shares may either be accepted in full, accepted for any lesser number, or rejected by the Company in consultation with the Underwriter. If any Application is rejected, in whole or in part, any surplus Application monies will be refunded, without interest.

The basis of allocation of Shares to Applicants will be determined by the Company in consultation with the Underwriter. Certain Applicants nominated by them may be given preference in allotment of Shares.



# 1 Details of the Offer

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## 1.9 Disbursement of application monies

All monies received with the Applications for Shares will be held by the Company in a separate bank account until the Shares are allotted. The account will be established and kept by the Company on behalf of Applicants. After the Shares have been allotted the application monies, including any interest on the account, will be paid to the Company.

Application monies will be fully or partially refunded where an Application is rejected or accepted in part only, or the Offer is withdrawn.

No interest will be paid on refunded amounts.

## 1.10 Allotment

The Company will allot the Shares as soon as possible after the Closing Date.

## 1.11 Rights attaching to Shares

The Shares issued under this Prospectus are fully paid ordinary Shares in the capital of the Company and will rank equally in all respects, at the time of issue, with all other existing Shares. The rights and liabilities attaching to all Shares are summarised in **Section 12.4**.

## 1.12 Australian Stock Exchange Listing

No later than seven days after the issue of this Prospectus, the Company will apply to the ASX for admission to the Official List and for existing Shares including Shares issued under the Exchange Agreement, the Shares issued under this Prospectus and the Shares issued in the US Private Placement, to be granted official quotation on the ASX.

In order to ensure that US persons do not purchase any Shares after quotation on the ASX, a number of procedures governing the trading and clearing of the Shares will be implemented, including the application to the Shares of the status of Foreign Ownership Restriction (FOR) securities under the ASTC Settlement Rules and the addition of the notation "FORUS" to the Shares' description on ASX trading screens and elsewhere. The FORUS notation will inform the market of the prohibition on US persons owning Shares after quotation on the ASX.

The fact that the ASX may agree to grant official quotation of the Shares is not to be taken in any way as an indication of the merits of the Company or the Shares offered. The ASX takes no responsibility for the contents of this Prospectus. Quotation, if granted, will commence as soon as practicable after the issue of holding statements to successful Applicants.

It is the responsibility of Applicants to determine their allocation prior to trading in the Shares. Applicants who sell Shares before they receive confirmation of their allotment, will do so at their own risk.

If permission for quotation of the Shares is not granted within three months after the date of this Prospectus, all Application Monies will be refunded without interest as soon as practicable.



# 1 Details of the Offer

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## 1.13 CHESS

The Company will become a participant in the security transfer system known as Clearing House Electronic Subregister System (“CHESS”), pursuant to the Listing Rules and the ASTC Settlement Rules.

Under CHESS, the Company does not issue share certificates to Shareholders. The Company will operate an electronic issuer sponsored sub-register and an electronic CHESS sub-register. Shareholders will receive a notice advising them of their Holder Identification Number in the case of a holding on the CHESS sub-register, or Security Holder Reference Number in the case of a holding on the issuer sponsored sub-register.

Following distribution of the initial transaction confirmation statements to all Shareholders, a holding statement will be provided to Shareholders at the end of the subsequent month during which there has been a movement in their shareholding. Shareholders may also request the Company to provide a statement at other times, although the Company may charge an administration fee in these circumstances.

## 1.14 Brokerage and Handling Fees

Brokerage and/or handling fees on application for Shares will be payable to member firms of the ASX or licensed investment advisors on such Application Forms bearing their codes and accepted by the Company. Any such brokerage or handling fees will be paid by the Underwriter out of its underwriting fee.

## 1.15 Withdrawal

The Company may at any time decide to withdraw this Prospectus and the Offer, in which case the Company will refund all Application Monies within 21 days of giving notice of its withdrawal. Any interest earned on Application Monies prior to withdrawal will belong to the Company.

## 1.16 Overseas Distribution

No action has been taken to register or qualify the Offer of Shares under this Prospectus, or otherwise to permit a public offering of Shares, in any jurisdiction outside Australia.

*Offer only made where lawful to do so*

The distribution of this Prospectus in jurisdictions outside Australia may be restricted by law. This Prospectus does not constitute an offer in any place in which, or to whom, it would not be lawful to make such an offer. Persons into whose possession this document comes should inform themselves about and observe any restrictions on acquisition or distribution of the Prospectus. Any failure to comply with these restrictions may constitute a violation of securities laws.

*No distribution or sale in the United States*

Neither this Prospectus nor the accompanying Application Form may be sent to any persons in the United States or otherwise distributed in the United States and the Shares may not be offered or sold in the United States or to or for the account or benefit of a US person.



# 1 Details of the Offer

Each applicant will be deemed, by submitting an application form in the General Public Application or participating in the Broker Firm offer, to make the representations and warranties set out in **Section 12.12** of this Prospectus.

## *Overseas Ownership and Resale Representation*

It is the responsibility of all Applicants to ensure compliance with all laws of any country relevant to their Application. The return of a duly completed Application Form will be taken by the Company to constitute a representation and warranty made by the Applicant to the Company that there has been no breach of such laws and that all necessary consents and approvals have been obtained. If the directors believe the Applicant is ordinarily a resident in the US, or is acting on behalf of a person or entity that is ordinarily resident in the US, the Board may reject the Applicant's Application.

### 1.17 Restricted Securities

The Directors anticipate that the ASX will require, as a condition of admitting the Company to the Official List, that the Company enters into restriction agreements in the format required by the Listing Rules, with the following persons, for the following numbers of securities to be escrowed for up to two years from the commencement of the official quotation of Shares:

| Person                       | Anticipated Number of securities                                     | Anticipated Period of escrow |
|------------------------------|--|------------------------------|
| Apple Tree Partners          | 87,005,221 Shares<br>\$1,420,000 of convertible notes                | Up to 24 months              |
| Other Heartware Inc. holders | 996,779 Shares   | Up to 12 months              |
| Dr R Fine                    | Up to 5,259,076 options  | Up to 12 months              |
| Rob Thomas                   | 500,000 incentive options<br>Up to 790,010 ESOP options <sup>1</sup> | Up to 24 months              |
| Dr Bennett                   | 250,000 incentive options  | Up to 24 months              |
| Dr Wade AM                   | 250,000 incentive options  | Up to 24 months              |
| Inteq Limited                | 500,000 incentive options  | Up to 24 months              |
| Stuart McConchie             | Up to 4,740,060 ESOP options <sup>2</sup>                            | Up to 24 months              |

<sup>1</sup> Rob Thomas has been issued 0.5% of the 10% ESOP, which is 790,010 ESOP options at the Upper Target Subscription.

<sup>2</sup> Stuart McConchie has been issued 3% of the 10% ESOP, which is 4,740,060 ESOP options at the Upper Target Subscription.

Each restriction agreement will prohibit the transfer of effective ownership or control of the Shares and Options to which it relates.

### 1.18 Investor Enquiries

This Prospectus provides information for potential investors in the Company, and should be read in its entirety. If, after reading this Prospectus, you have any questions as to how to subscribe for Shares under this Offer, please consult your professional advisor.

Additional copies of the Prospectus or further advice on how to complete the Application Form can be obtained by telephoning or visiting:

**Emerging Growth Capital Pty Limited**  
Level 3, 1 Castlereagh Street  
Sydney, NSW 2000

Telephone: (02) 9222 1991  
[www.egcapital.com](http://www.egcapital.com)



## 2 Information on the Business

### 2.1 Overview

HeartWare's products are circulatory assist devices, which address heart failure, one of the largest medical needs in developed nations, affecting over 10 million people. In the United States alone, nearly five million patients suffer from heart failure, and 550,000 new cases are diagnosed each year. According to the Australian Institute of Health and Welfare *"There are no Australian data on the incidence and prevalence of heart failure in the Australian population or among at-risk population sub-groups. However, based on overseas findings... at least 300,000 Australians have chronic heart failure... with 30,000 new cases diagnosed each year"*. HeartWare believes that advances in heart failure treatment are only beginning to make a meaningful impact on mortality. The one year survival rate for patients with severe heart failure is 25%.

Based upon proprietary design features of small size, device pumping capability (full cardiac output) and other features that should enhance durability and reliability, HeartWare believes that its range of circulatory assist devices should perform better than those of known competitors.

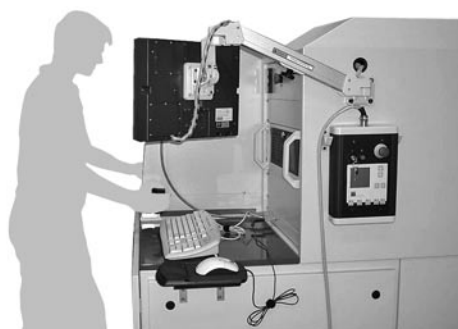
HeartWare estimates that the available market for its first product, the HVAD, is approximately 100,000 patients or \$10 billion, while its subsequent miniaturised product, the MVAD, is expected to address an even larger patient population.

The Company intends to continue the commercialisation of the first of its circulatory assist devices, the HVAD, which is expected to commence human trials in late 2005. The Company is seeking to raise up to approximately \$35 million in order to fund Australian and EU human trials. Subject to the successful outcome of the HVAD human trials, HVAD regulatory approvals and sales in Australia and the EU are anticipated during the third quarter of 2007.

HeartWare's operations include a US Operations Centre in Miramar, Florida, USA, and HeartWare intends to establish an Asia Pacific Operations Centre in Sydney, Australia.

- The Australia Centre is being established to co-ordinate Australian clinical trials and enable HeartWare to optimise its access to and service of the Asia Pacific markets, particularly China, Japan and South Korea.
- The Miramar Centre will continue to develop product enhancements and new prototypes, will serve as HeartWare's main business development, regulatory and marketing hub, with easy access to the large USA and European markets and will become the Company's primary manufacturing facility.

The HeartWare Management Team and Board have extensive experience in technology development, regulatory affairs, clinical trials, and marketing and sales. HeartWare has assembled an Advisory Board that comprises heart surgeons and heart failure cardiologists. The Advisory Board has provided and is anticipated to continue to provide input regarding technology and product development, surgical implantation techniques, clinical trial protocols and patient care and quality of life issues associated with the Company's products.



Laser welder

## 2 Information on the Business

### 2.2 Current Product: the HVAD

HeartWare believes the HVAD to be the smallest, most efficient, full output circulatory assist device currently entering commercialisation.

The HVAD is designed to be implanted in patients with advanced heart failure. The device is designed to support one or both sides of the heart and to be used in smaller patients than currently approved devices. HeartWare believes that the HVAD is the only full output, long term, implantable circulatory assist device that can be implanted in the space directly surrounding the heart (pericardial space), which should provide the benefit of enabling a shorter, less extensive implantation procedure in most patients. Longer surgical procedure time generally results in increased patient morbidity and mortality and correspondingly increased treatment cost.

HeartWare has worked closely with cardiac surgeons, including members of its Advisory Board, to develop a surgical kit containing disposable tools and fixtures to facilitate HVAD implantation. Based upon feedback from cardiac surgeons who have implanted the device in animals, HeartWare estimates that the time required to implant an HVAD will be approximately two hours in patients who have not had prior heart surgery. HeartWare believes that this compares favourably with the longer procedure times required for larger, more complex devices which can be five hours or longer.

HeartWare believes that the HVAD, once approved, could potentially offer patients and their treating physicians important benefits, including:

A shorter, less traumatic surgical implantation procedure leading to:

- faster recovery and hospital discharge
- less severe post operative complications

Improved quality of life resulting from:

- reduced levels of anticoagulation medication
- reduced risk of stroke
- reliability and durability of the device

HeartWare's  
HVAD and  
a FDA  
approved  
device



## 2 Information on the Business

### 2.3 Next Generation Products: MVAD and PedVAD

HeartWare is developing its next generation of products in parallel with its first product, the HVAD. Based upon the same core technologies underlying the HVAD and upon a new proprietary technology, HeartWare's future products under development are far smaller than the HVAD and thus have the potential to further expand the Company's total addressable market.

*MVAD: A miniaturised device intended for chronic heart failure patients*

The current prototype of the MVAD is approximately one tenth the size of the HVAD. HeartWare believes that its MVAD will have identical blood flow characteristics to the HVAD and will support the heart's full cardiac output. The MVAD is expected to require only minimally invasive surgery and/or a catheter based procedure to be implanted.

The relative simplicity of the MVAD implantation procedure is expected to facilitate its use by cardiologists, either working independently or with cardiac surgeons. This may allow HeartWare to expand its market to earlier stage chronic heart failure sufferers, a market which HeartWare estimates to be 250,000 patients worldwide.

*PedVAD: For infants with heart failure*

The MVAD is expected to serve as a basis for the development of HeartWare's Paediatric Ventricular Assist Device, the PedVAD, for use in small children.

The Artificial Heart Fund ("AHF"), a specialist independent UK charity organisation, is committed to accelerating the development of circulatory assist devices for paediatric patients. AHF has indicated it will accept a grant funding application from HeartWare and will assist HeartWare to access other funding sources for the PedVAD.



Lifecycle tester  
at HeartWare

### 2.4 Corporate Structure

HeartWare, Inc. owns the technologies underlying its circulatory assist devices, which have been in development for approximately ten years. To date approximately \$46 million (US\$32 million) has been invested and committed, initially in a predecessor company, the assets of which HeartWare, Inc. acquired in 2003.

The Company entered into a Securities Exchange Agreement with HeartWare, Inc., Apple Tree Partners and other holders of HeartWare, Inc.'s Series B Convertible Preferred Stock on 13 December 2004 to acquire the Series B stock on issue by HeartWare, Inc. (the "**Acquisition**"). The common stock, of which none is on issue, and Series B stock are the only voting stock of HeartWare, Inc. and the Series B stock only is entitled to receive dividends if dividends are declared on the common stock. HeartWare, Inc. also has existing Series A-1 and Series A-2 stock, which will remain on issue after the Acquisition. This Series A-1 and Series A-2 stock has no rights other than a potential liquidation distribution if HeartWare, Inc. is ever sold or liquidated and certain statutory voting rights under Delaware state law.

HeartWare believes that a location in Australia offers the following advantages for the achievement of HeartWare's clinical and operating objectives:

- Establish an Australian base of operations from which to conduct a combined HVAD clinical trial in Australia and the EU for both bridge to transplant and destination therapy indications. HeartWare believes that it will likely be able to undertake destination therapy clinical trials earlier and less expensively in Australia and the EU than elsewhere — thereby achieving a quicker route to market for its first product.
- Take advantage of what HeartWare believes to be an expedited clinical trial process in Australia and Europe as compared to the US.
- Provide a platform to launch its products into Asia Pacific markets.

HeartWare believes it will have competitive advantages as an Australian listed company with a US operations centre and team of US executives experienced in marketing and regulatory areas.

#### *US operations and development centre – Miramar, Florida*

The US operations base of HeartWare is in Miramar, Florida, a major hub for biomedical companies and research in the United States. This base provides access to skilled staff, suppliers and local infrastructure including numerous universities with biomedical programmes. This US base also provides ready access to the American and European markets.

The HeartWare operations base is a 1,383 square metre (14,922 square feet) manufacturing facility with electronics, mechanical and quality assurance laboratories as well as controlled manufacturing space and a clean room. This facility will continue to be the main technology development and manufacturing centre for HeartWare's products through both the trial and marketing stages.

#### *Corporate Head Office and Asia Pacific support centre – Sydney, Australia*

The Company's Chief Executive Officer will be based at the Sydney Head Office and will divide his time between the Australian and US offices. The Company's Chairman will also be based in Sydney, as will at least two additional directors.

The Company plans to manage its finance and strategic functions from the Sydney Head Office, along with all compliance, corporate governance, investor relations and Australian regulatory requirements. The Australian office will initially co-ordinate Australian clinical trials and regulatory approvals, but eventually will focus on identifying partners, suppliers and potential distribution opportunities in Australia and the Asia Pacific markets.



In addition, as part of its role as the regional centre for the Asian Pacific markets, particularly China, Japan and South Korea, this office will co-ordinate training and technical support.

### 2.5 Relationship with Artificial Heart Fund

The Artificial Heart Fund (“AHF”) is a UK charity established to further the development of effective treatments for heart failure patients, in particular through the development and implantation of circulatory assist devices.

AHF has reviewed circulatory assist products, technologies and companies, and has expressed interest in the HeartWare product family and in particular the development of HeartWare’s PedVAD device for paediatric applications. AHF has stated that it intends, where possible, to provide assistance to HeartWare in a number of areas:

- Obtaining support in the United Kingdom for an EU destination therapy trial.
- Obtaining grant funding, of up to £1.5 million from AHF, to offset the costs of any clinical or animal trials which take place in the United Kingdom and possibly other Commonwealth countries. This funding could include purchasing HVADs for such trials.
- Securing reimbursement for the HVAD, once HVAD achieves regulatory approval.
- Obtain grant funding in support of the development of PedVAD.
- Distributing PedVADs in the EU under a compassionate access program once the PedVAD receives regulatory approval.

### 2.6 Industry Overview

Heart failure is a major worldwide disease. The majority of patients with heart failure have multiple underlying cardiovascular disorders, the most common of which are atherosclerosis, myocardial infarction, hypertension, cardiomyopathy, and arrhythmia.

Despite advances in heart failure treatment, physicians estimate the one year survival rate for severe heart failure patients to be 25%.

A commonly accepted method for categorising chronic heart failure is the New York Heart Association Classification, which identifies four levels in a steady progression of the disease.

#### *Heart failure*

| Class I<br>(least severe cases)  | → Class II  | → Class III  | → Class IV<br>(most severe cases)  |
|--|---|--|--|
| <ul style="list-style-type: none"> <li>• 40% of patients</li> <li>• No physical limitation</li> <li>• Little to no drug therapy</li> </ul> | <ul style="list-style-type: none"> <li>• 25% of patients</li> <li>• Some physical limitation</li> <li>• Drug therapy</li> </ul> | <ul style="list-style-type: none"> <li>• 25% of patients</li> <li>• Marked limitation of activity</li> <li>• Drug therapy, biventricular pacing, or surgery</li> </ul> | <ul style="list-style-type: none"> <li>• 10% of patients</li> <li>• Symptoms at rest</li> <li>• Candidates for transplant and LVADs</li> </ul> |



## 2 Information on the Business

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Heart failure results from the progressive deterioration of the pumping function of the heart, resulting in its inability to meet the metabolic demands of the body. The mechanical changes associated with heart failure may result in a weak and dilated heart muscle or, conversely, a stiff and restrictive heart muscle. A multitude of diseases can lead to heart failure including heart attack, atherosclerosis and less frequently, viral infections. In each of these cases, the heart's pumping function is adversely altered and rendered progressively ineffective in meeting the body's needs.

Many symptoms and conditions associated with heart failure can often be treated, but in many cases the underlying functional impairment of the heart cannot. Once heart function is impaired past a certain point the heart becomes weakened or stiff and it tries to compensate; yet, by a complex process, often the heart further enlarges and becomes less effective at pumping blood. This vicious cycle is generally irreversible and often culminates in death.

Heart failure can impact either the left or right ventricle:

- **Left-sided heart failure** – occurs when the left ventricle cannot adequately pump oxygen rich blood from the heart throughout the body. Even though the right side of the heart adequately pumps blood to the lungs, if the left side of the heart cannot keep up, pressure backs up in the heart's left atrium, causing fluid from the lung vasculature to seep into the lung air spaces.

The main symptoms of this fluid build up include shortness of breath, fatigue and coughing, especially at night or while lying down. Fluid in the lungs leads to congestion, hence the term "congestive heart failure" ("CHF").

- **Right-sided heart failure** – occurs when the right ventricle cannot pump adequately. The blood returning to the right ventricle backs up, causing fluid to build up in the vasculature and leak into tissues, resulting in a condition known as oedema, most often in the lower extremities or other organs, such as the liver.

### *Treatment options*

Current treatments for heart failure include the following:

- **Drugs**

A drug regimen of beta blockers, diuretics, digitalis and angiotensin-converting enzymes (ACE inhibitors) aim to improve the effectiveness of the heart's contractions and slow CHF progression. Some investigations have suggested that the increase in survival is limited and that drug treatments merely delay the advance of CHF. Although drug therapy for heart failure can improve the quality of life and also modestly prolong survival, it is well established that many of the currently available approaches do not represent satisfactory treatment options for a large number of patients.

- **Heart Transplantations**

Heart transplantation has become an effective and accepted surgical procedure which can result in end-stage heart failure patients resuming relatively normal lives for a period usually expected to be up to ten years. This procedure is limited due to the lack of available donor hearts. There are approximately 3,000 heart transplants performed each year.

- **BiVentricular Pacing (BVP)**

BVP devices are designed to electrically resynchronize the contractions of the left and right ventricles. The MIRACLE (Multicenter InSync Randomized Clinical Evaluation) trial demonstrated that, of the CHF patients eligible for electrical pacing, almost one third showed no improvement or became worse after treatment. In those patients who responded, the heart's pumping ability improved by approximately 5%.

### ○ Coronary Artery Bypass Graft Surgery

This is a surgical procedure to route blood flow around a blockage or narrowing of an artery located on the heart. This procedure is considered in heart failure patients primarily when there is evidence of 'hibernating' heart muscle that will exhibit improved function with restoration of normal blood flow. Improvements have resulted following bypass in such cases; however, the inability to accurately identify suitable patients limits the applicability of the procedure.

### ○ Heart Restraint Devices

These are sock like devices placed around the dilated heart, which are intended to reduce wall stress and improve cardiac function. While this treatment approach may prove promising, study results are only just becoming available.

### ○ Cell-Based Therapies

Currently at an early research stage, cell based therapies may ultimately provide a cure for the underlying myocardial dysfunction in CHF. The Company believes that viable cell based CHF therapies are at least a decade away.

### ○ Intra-aortic Balloon Pumps (IABP)

IABPs have been in clinical use since the late 1960's and are inserted by a cardiologist or surgeon to reduce acute heart failure symptoms or improve cardiac output. A balloon-tipped catheter is placed in the aorta, where the balloon inflates and deflates in counter pulsation with the heart's natural contractions. Clinically, these pumps are most often used for temporary support in patients with acute reversible heart failure.

### ○ Extra-aortic Balloon Pumps (EABP)

These devices are applied to the external surface of the ascending aorta, with advantages of ease of surgical implantation and no contact with circulating blood. Several of these devices are in or expected to enter clinical trials. HeartWare believes these devices do not provide sufficient forward blood volume for patients in end stage heart failure and may be more invasive than the Company's products planned for treatment of earlier stages of heart failure.

### ○ Total Artificial Heart (TAH)

Similar to cardiac transplantation, a TAH is implanted to 'replace' the patient's native heart. TAHs are large, complicated devices and the Company believes they will be used only in a very minor subset of end-stage CHF patients.

### ○ Circulatory Assist Devices

In 2001, the REMATCH clinical trial for "Randomized Evaluation of Mechanical Assistance Device for the Treatment of Congestive Heart Failure," was published in the New England Journal of Medicine. The trial concluded that *"The use of a left ventricular assist device in patients with advanced heart failure resulted in a clinically meaningful survival benefit and an improved quality of life. A left ventricular assist device is an acceptable alternative therapy in selected patients who are not candidates for cardiac transplantation"*.



## 2 Information on the Business

### HeartWare's family of circulatory assist devices

HeartWare's circulatory assist devices are designed to take over some or all of the pumping function of the heart in chronic heart failure patients. These patients may require either a bridge to transplantation or a permanent or destination therapy.

HeartWare is developing a family of circulatory assist devices designed to treat patients in Class III and Class IV chronic heart failure. For destination therapy, it is important that the device be durable and reliable. HeartWare's devices are designed to be durable for long term support, while still providing full cardiac output.

### 2.7 Market Size

Heart failure is a leading cause of death in the developed world. In the United States, nearly five million patients suffer from heart failure, and 550,000 new cases are diagnosed each year (Heart Disease and Stroke Statistics-2004 Update, American Heart Association). According to the Australian Institute of Health and Welfare: *"There are no Australian data on the incidence and prevalence of heart failure in the Australian population or among at-risk population sub-groups. However, based on overseas findings... at least 300,000 Australians have chronic heart failure... with 30,000 new cases diagnosed each year"*.

Set out in the Table below is the prevalence of chronic heart failure in the major markets, as at 2001.

|                       | US    | Japan | France | Germany | Italy | Spain | UK   |
|-----------------------|-------|-------|--------|---------|-------|-------|------|
| Chronic heart failure |       |       |        |         |       |       |      |
| Patients in 000's     | 5,607 | 2,400 | 500    | 1,234   | 480   | 210   | 883  |
| Percentage            | 2.0%  | 1.9%  | 0.8%   | 1.5%    | 0.8%  | 0.5%  | 1.5% |

(Source: Treatment Algorithms 2002: Heart Failure, Datamonitor).

HeartWare believes that the global CHF market is approximately twice that of the US market or 10 million patients. HeartWare's target markets are heart failure patients in Class III or IV, of whom HeartWare estimates that approximately 10% could be assisted by a circulatory assist device.

#### End stage heart failure market (NYHA Class IV): the HeartWare HVAD

HeartWare estimates that there are 1,000,000 NYHA Class IV heart failure patients worldwide of whom approximately 100,000 represent HeartWare's target market. Based on HeartWare's current planned sales price of \$100,000 (US\$75,000) per patient kit, this total available market exceeds \$10 billion (US\$7 billion).

Heart failure patients can be further subdivided into those suitable for either "destination therapy" or "bridge to transplant therapy":

- Destination therapy refers to the permanent or quasi permanent use of a circulatory assist device in patients suffering from end stage heart failure. It is a category comprising the majority of VAD eligible heart failure patients and is HeartWare's target market for the HVAD.
- Bridge to transplant therapy refers to the temporary use of a circulatory assist device in end-stage heart failure patients awaiting a heart transplant. There are approximately 3,000 heart transplant procedures conducted each year. A proportion of these patients will require a bridge to transplant, representing an estimated market potential of up to \$100 million.

While destination therapy represents HeartWare's primary target market, obtaining approval for bridge to transplant treatment is generally considered to be an important interim regulatory step.

### *Chronic heart failure market (NYHA Class III): the HeartWare MVAD*

A miniaturised permanent circulatory assist device could become a viable treatment for those patients in NYHA Class III heart failure. HeartWare expects that the MVAD, the prototype of which is one tenth the size of the HVAD, could potentially address the needs of this market.

HeartWare estimates that there are approximately 2,500,000 NYHA Class III heart failure patients worldwide of whom approximately 250,000 represent HeartWare's target market.

### 2.8 Customers

HeartWare's customers are those medical professionals who refer patients for the device, or who implant or pay for the device, as well as the patients themselves. HeartWare believes that the distinctive features of its products are likely to attract strong interest from all key stakeholders, as summarised below.

#### *Treating doctors*

Three groups of doctors are generally involved in the treatment of circulatory assist device patients:

- **Cardiologists**

Cardiologists manage patients using medicines, and work with interventional cardiologists and heart surgeons to ensure the continuity of care of their patients who could benefit from device treatments. Typically cardiologists are viewed as an important source of patient referrals for surgeons and interventionists.

- **Heart Surgeons**

Heart surgeons implant circulatory assist devices and, as such, they represent HeartWare's principle HVAD target market. Based upon discussions with HeartWare's Advisory Board, HeartWare expects heart surgeons will embrace the size and performance advantages of its devices, once they are approved.

- **Interventional Cardiologists**

Interventional cardiologists typically work with specialised catheter-mounted instruments, which they thread through the vasculature in order to perform cardiovascular treatments. HeartWare anticipates that interventional cardiologists will become a key target market for its miniaturised devices, particularly the MVAD, which is designed to be implanted via minimally invasive techniques.

#### *Hospitals*

Hospitals and hospital groups are responsible for purchasing circulatory assist devices and for providing the operating and patient care facilities.

HeartWare intends to develop strategic relationships with key hospital administrators. To this end HeartWare will draw on the extensive experience of its Advisory Board members.



## 2 Information on the Business

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### *US Reimbursement*

In the US, hospitals and doctors generally rely on third-party payers, such as Medicare, private health insurance plans and health maintenance organisations to reimburse all or part of the cost of medical devices and the related surgical procedures.

In 2001, the US Centre for Medicare and Medicaid Services (CMS) filed a notice that implantable ventricular assist devices would be reimbursed under Diagnosis Related Group (DRG) 103, which is the highest DRG that covers heart transplantation. Using the new published payment rates, the average Medicare payment to CMS certified centres has increased to an average of US\$136,000. HeartWare believes that its products will be Medicare eligible and therefore that they should be entitled to reimbursement. Reimbursement is expected to apply during US clinical trials once an IDE has been approved.

Several insurance providers have also implemented US policies for circulatory assist devices, including Blue Cross and Blue Shield.

### *European Reimbursement*

Reimbursement in the EU varies from country-to-country and often hospital-to-hospital. HeartWare believes that numerous hospitals have well established budgets to purchase circulatory assist devices and this decision is often driven by key doctors.

The Artificial Heart Fund (AHF) has stated its intent to work with HeartWare to obtain reimbursement approval for the HVAD from the UK National Health Service.

## 2.9 Revenue

HeartWare expects to derive revenue primarily from the sale of devices and ancillary supplies.

- Sales of HVAD patient kits and centre implementation kits

HeartWare intends to sell its devices based on a price list for patient kits and hospital kits. The Company intends to manage the price of its products in accordance with the applicable reimbursement rates available from health funds and government bodies.

In markets with specific local requirements and custom, such as Asia, HeartWare will consider appointing resellers on a country by country basis. It is expected that an appointed reseller will pay HeartWare a proportion of the sale price in return for arranging and managing local regulatory approvals and support activities.

- Sales of ancillary supplies

HeartWare plans to sell additional batteries, monitors and other ancillary supplies to patients and hospitals as required.

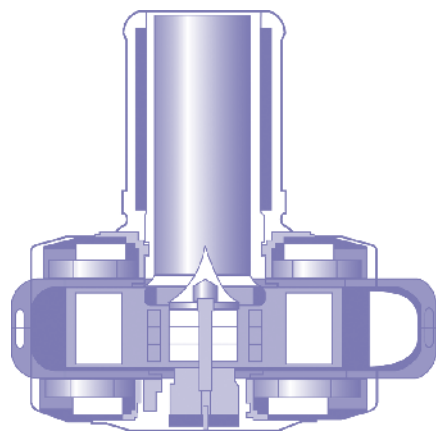
# 3 The Technology

## 3.1 Technology Overview

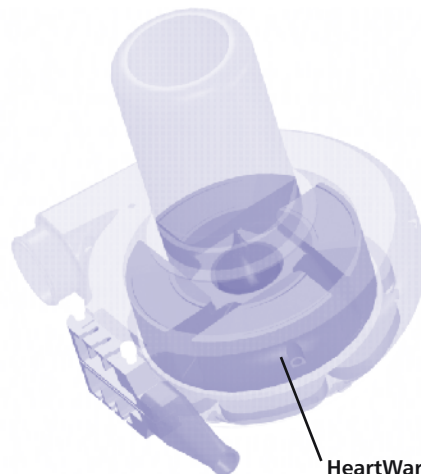
HeartWare's technology is based on the use of a wide bladed impeller designed to achieve optimum performance and haemocompatibility, size minimisation, long term reliability and overall system efficiencies.

The impeller is the only moving part in the HeartWare device. The impeller is held in place by a proprietary hybrid magnetic and hydrodynamic bearing system. The wide blades of the impeller contain large motor magnets, so the same space is used for pump and motor elements, achieving design efficiencies. The rare earth magnets in the impeller do not require electricity in order to induce their magnetic effect, thereby minimising the need for wires and connections, further simplifying the design and improving reliability. The result is a compact, energy efficient device, which is wearless, reliable and shock resistant, designed to provide full cardiac output with optimal haemocompatibility.

Important additional features of the technology include two motor stators providing redundancy, a proprietary integrated inflow cannula enabling pericardial implantation and electrical leads based on pacemaker technology.



Slice view of HeartWare's pump technology



HeartWare's Impeller

### *HVAD technology*

HeartWare's first device, the HVAD, has a volume of 45 cubic centimetres (cc) and a mass of 145 grams. The Company believes that no other circulatory assist device combines the HVAD's characteristics of full cardiac output, wearless and durable design, small size and ease of implant.

To date, HeartWare has performed a series of pre clinical trials of its HVAD in vitro and in animals. The design development animal trials for the HVAD were conducted to assess anatomical fitting, design, pump mechanics and long term compatibility with blood components and were completed in 2001. Currently, pre good laboratory practice ("GLP") animal trials are being conducted and GLP animal trials for the HVAD are planned to commence in early 2005.

### *Miniaturisation of the technology: MVAD and PedVAD*

One of the features of HeartWare's technology is the expected ability to further miniaturise its devices without compromising system output or efficiency. HeartWare has commenced development of its MVAD, which is approximately one tenth the size of the HVAD. Further development and animal trials will be required before the MVAD is able to be implanted in humans.

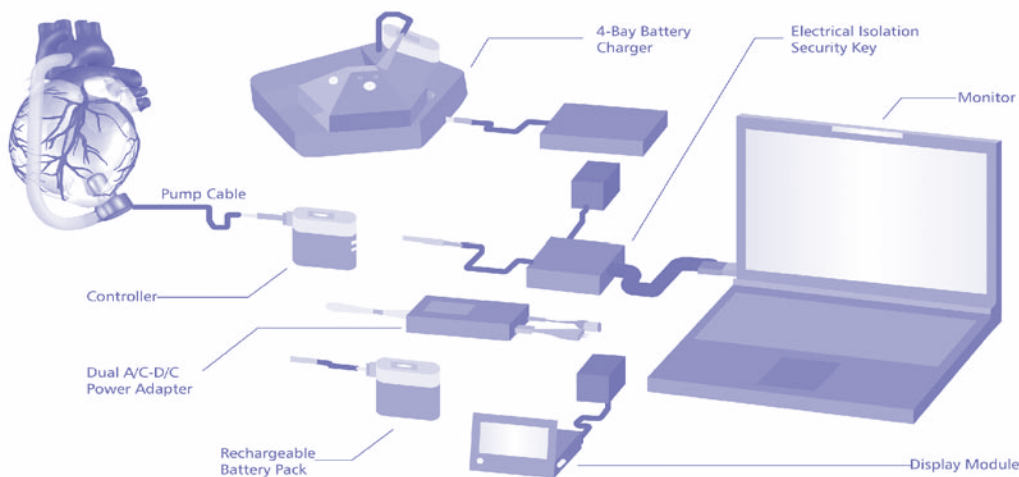
The ability to miniaturise its devices underpins HeartWare's plans for future products which the Company believes will be able to be implanted by minimally invasive surgical techniques.

# 3 The Technology

## 3.2 Surgical Implantation

HeartWare estimates the HVAD surgical implantation procedure will take approximately two hours in a patient who has not undergone previous chest surgery. HeartWare has developed a simple to use, disposable, “surgical kit” that contains custom designed tools required for implanting its device. The HVAD implantation procedure, developed by cardiac surgeons, is expected to proceed as follows:

- The patient’s chest is opened and the heart is exposed.
- The driveline, which is approximately 3 mm in diameter, is tunnelled through the body and connected to the external controller.
- The outflow graft is sewn onto the aorta.
- The sewing ring is attached to the heart wall.
- Using HeartWare’s custom designed coring tool, a hole is made in the ventricle within the area defined by the sewing ring.
- The proprietary inflow cannula, which is integrated into the pump, is inserted into the ventricle through the sewing ring and the device is locked into position via a simple ratchet mechanism.



Artist’s rendering of the HeartWare system including device, patient controller and hospital monitoring equipment.

## 3.3 Patient Monitoring and Control of Pump

The ongoing performance of the implanted device will be monitored by the attending doctor so that device control settings can be fine tuned according to patient need. The HeartWare controller design incorporates sufficient flexibility to accommodate a range of patient specific conditions.

HeartWare’s technology includes proprietary feedback control to monitor patient blood flow requirements and automatically adjust the impeller speed within physician specified guidelines. HeartWare devices can also be used on a fixed output setting providing physicians with flexibility in defining patient treatment parameters.



## 3 The Technology

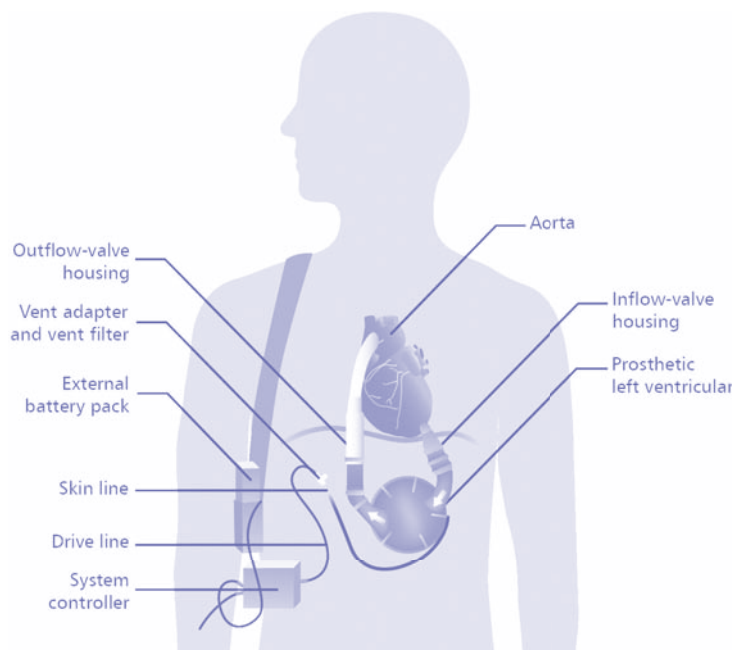
### 3.4 Competition and other technology

#### *First generation: implantable volume displacement blood pumps*

The “first generation” circulatory assist devices or left ventricular assist devices (“LVADs”) were designed originally to replicate the heart’s normal mechanical activity. These pulsatile volume displacement pumps are relatively large and bulky. They are implanted in the abdomen, with inflow and outflow cannulas routed through the diaphragm to the patient’s heart.

The HeartMate XVE LVAS™, a volume displacement pump marketed by Thoratec Corporation, has FDA approval. Other first generation LVADs include the Novacor™ device, marketed by World Heart Corporation for bridge to transplant and Arrow International’s LionHeart™, which has received CE Mark.

HeartWare believes that the size, weight and limited durability of these first generation LVADs, could limit their clinical application as destination therapy devices.



First-generation devices are implanted in the patient’s abdomen.

#### *Second generation: implantable continuous flow LVADs using mechanical bearings*

A range of second generation pumps are being developed that move blood via a rotary or continuous flow mechanism. These pumps are non pulsatile, do not require valves and have fewer moving parts. They are typically expected to have a lower risk of mechanical failure and lower energy requirements.

The second generation LVADs are characterised by their use of contacting bearings. HeartWare believes that these bearings typically wear out over a period of two to five years. When bearings wear they typically diminish LVAD performance and can ultimately cause an LVAD to fail. To avoid blood clotting, which can be a complication associated with contacting bearings, typically patients must take anticoagulation medicine. Such medicines can cause serious side effects.

# 3 The Technology

Second-generation continuous flow blood pumps are being developed by groups including Jarvik Heart, MicroMed Technology, Inc. and Thoratec Corporation with its 'HeartMate II™'. All these devices are implanted in the abdomen with the exception of the Jarvik 2000, which is implanted directly within the left ventricle. Only MicroMed DeBakey's LVAD has received regulatory approval, with its European CE mark for bridge to transplant therapy.

### Third generation: implantable continuous flow LVADs using no mechanical bearings

Third generation pumps feature wearless bearings to improve system longevity. HeartWare believes its HVAD technology to be the best of the third generation designs.

Several third generation blood pumps are currently in development, including Thoratec's 'HeartMate III™', Arrow Corporation's 'CorAide™', Ventracor Limited's 'VentrAssist™', MedQuest Inc.'s 'HeartQuest™', Berlin Heart AG's 'Incor™', and Terumo's 'DuraHeart™'.

None of the third generation devices currently under development is as small as the HVAD and none can be implanted in the pericardial space. HeartWare believes from animal trials and discussions with the Advisory Board that its HVAD design could potentially offer other advantages over the third generation devices under development, including improved haemocompatibility, ease of implantation, reliability and energy efficiency.

### Evolution of LVADs

HeartWare's view of LVAD evolution and a comparison of various device features based on available public information is set out below.

|                 |   | Volume   | Mass                       | Pericardial Placement | Wearless    | Expected Ability to miniaturise |
|-----------------|---|--|----------------------------|-----------------------|-------------|---------------------------------|
| LVAD Technology | <b>First Generation</b><br>Volume displacement<br>• Thoratec HeartMate I<br>• WorldHeart Novacor<br>Rotary            | Not included as HeartWare believes these devices have limited clinical application for destination therapy |                            |                       |             |                                 |
|                 | <b>Second Generation</b><br>Axial<br>• Jarvik 2000<br>• MicroMed DeBakey<br>• Thoratec HeartMate II<br>• Berlin Incor | 25cc<br>37cc<br>63cc<br>60cc   | 85g<br>95g<br>281g<br>200g | N<br>N                | N<br>N      | N<br>N                          |
|                 | <b>Third Generation</b><br>Centrifugal  |  |                            |                       |             |                                 |
|                 | <b>Active Maglev</b><br>• MedQuest HeartQuest<br>• Terumo DuraHeart<br>• Thoratec Heartmate III                       | 155cc<br>150cc<br>195cc  | 540g<br>420g<br>500g       | N<br>N<br>N           | N<br>N<br>N | N<br>N<br>N                     |
|                 | <b>Passive</b>  |  |                            |                       |             |                                 |
|                 | <b>Radial Hydrodynamic Support</b><br>• Arrow CorAide   | 200cc  | 300g                       | N                     | Y           | N                               |
|                 | <b>Radial &amp; Axial Hydrodynamic Support</b><br>• Ventracor VentrAssist   | 122cc  | 298g                       | N                     | Y           | N                               |
|                 | <b>Axial Hydrodynamic Support plus MagLev</b><br>• HeartWare HVAD   | 45cc   | 145g                       | Y                     | Y           | Y                               |



## 4 Product Strategy

### 4.1 HVAD regulatory approval and product launch

HeartWare intends to conduct a series of human clinical trials for its HVAD before rolling out the product in Australia and the EU, moving then to the United States.

#### *Combined Australian and EU trials for TGA and CE mark approvals*

In late 2005 HeartWare expects to initiate a combined destination therapy and bridge to transplant multi centre clinical trial in Australia and the EU with the first implant to take place in early 2006. The trial is expected to include approximately 25 patients in an estimated 7 centres.

- Australian 'destination therapy' patients

In Australia, HeartWare plans to focus on destination therapy patients. The Company believes Australian regulations are comparable to those in Europe. HeartWare therefore intends to aggregate Australian and EU clinical trial results into a single data set for TGA and CE mark submissions. This data will also be used to support US FDA regulatory applications. HeartWare has commenced discussions with Australian cardiac surgeons with experience implanting LVADS, including surgeons based at Royal Perth Hospital and St Vincent's Hospital Sydney.

- EU 'destination therapy' patients

HeartWare plans to work with Mr. Stephen Westaby as one of its principal investigators for the EU clinical trials of its HVAD. Mr Westaby works at the John Radcliffe Hospital at Oxford University in the United Kingdom and is a member of HeartWare's Advisory Board. The Artificial Heart Fund has stated its intention to endorse the HVAD to the UK National Health Service, with the objective of obtaining reimbursement for HVADs used in UK clinical trials.

- EU pilot 'bridge to transplant' patients

HeartWare plans to initiate a pilot "bridge to transplant" trial, designed in accordance with FDA protocols, most likely at the Vienna General Hospital under the supervision of Dr Georg Wieselthaler, a member of HeartWare's Advisory Board. This trial is expected to be designed to enable HeartWare to commence bridge to transplant clinical trials as soon as possible in the US. The bridge to transplant indication is currently considered a US FDA prerequisite to destination therapy trials and HeartWare believes that successful results in an EU pilot trial will accelerate the Company's ability to begin human implantation in the US.

#### *US human trials and FDA approval*

Using the pilot HVAD study results from Australia and the EU, HeartWare plans to conduct HVAD pivotal human trials in the United States. The first trial is expected to be a multi centre trial for bridge to transplant patients, with a second multi centre destination therapy trial to be conducted thereafter.

Several of the members of HeartWare's Advisory Board are expected to become investigators for US human trials, including:

- O.H 'Bud' Frazier, MD - Texas Heart Institute
- Steven Boyce MD - Washington Hospital Center
- Laman Gray Jr. MD - University of Louisville



## 4 Product Strategy

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### *HVAD product package*

HeartWare intends to supply the HVAD and its related components in one of three separate 'kits', purchased in combination or separately depending upon intended use:

- An HVAD patient kit which includes the HVAD, patient control unit, battery pack, battery charger and AC power supply, and also the necessary surgical implant tools.
- A centre support kit (for each implanting facility) which includes a clinical monitor, backup controller, batteries and accessories.
- A centre implementation kit (for facilities initiating HVAD implant programs) which includes a contracted number of patient kits, a centre support kit and associated training materials.

### *HVAD product sales and distribution*

Once regulatory approvals are in place HeartWare plans to:

- Use selected clinical trial centres in Australia, the EU and the US as training centres for the HVAD implantation procedure
- Work with hospital administrators, cardiac surgery centres, cardiologists, surgeons, physicians, insurers, government and industry representatives, to promote the treatment benefits of its products
- Recruit and train a direct sales force to target US, Canadian, Australian and European buyers
- Engage international distributors to supplement direct sales activities, particularly in select European countries and parts of Asia Pacific. The Australia operations centre will serve as a base of operations to enter the Asian market for the HVAD. The country of greatest emphasis will be Japan, whose medical device market is the second largest in the world.

## 4.2 Future product rollout

In parallel with the clinical development of the HVAD, HeartWare plans to advance the development of its next generation products.

### *MVAD: expediting access to the chronic heart failure market*

HeartWare has developed a prototype of the MVAD, which is designed to provide full cardiac output and is approximately one tenth the size of the HVAD. A portion of funds raised under the Offer will be applied to further MVAD development. The first MVAD animal trials are targeted for 2006.

### *PedVAD: addressing the needs of children with heart failure*

The PedVAD will be based upon the Company's MVAD technology. The paediatric device is anticipated to reach the clinic in parallel with the MVAD. While paediatric heart failure is not a large market, HeartWare believes it is an important medical need.

### 4.3 Manufacturing Strategy

HeartWare's US operations base in Miramar, Florida, USA, is a 1,383 square metre (14,922 squarefeet) facility dedicated to the development and manufacture of HeartWare's products. The facility includes electronics, mechanical and quality assurance laboratories as well as controlled manufacturing space. Prior to the first human trials, HeartWare plans to register with the FDA as a manufacturing facility and to seek ISO 13485 2003 certification.

HeartWare believes that the Miramar facility will be able to produce the quantities of HVADs required for the planned clinical trials and initial commercialisation. Over time, HeartWare expects that it will expand its manufacturing capacity in line with demand for its products.

Certain components of the HVAD are manufactured by external suppliers in FDA registered facilities. HeartWare will conduct final assembly, quality assurance, packaging and distribution. The strategy of outsourcing selected manufacturing processes is intended to minimise capital and operating costs while maintaining the required quality standards.

HeartWare expects to implement steps to further reduce manufacturing costs as volumes increase.

HeartWare  
expects  
less severe  
post operative  
complications



## 5 Regulatory

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### 5.1 Regulatory Overview

Medical device regulations are enforced in Australia by the Therapeutic Goods Administration (“TGA”), in the US by the US Food and Drug Administration (“FDA”), and in Europe by the European Medical Device Directives. Regulatory requirements also include ISO-13485-2003 compliance for the manufacturing and assembly of medical devices.

Various regulatory approvals will also be required as product development advances into commercialisation. Following launch, there will be an ongoing requirement to file yearly reports with the FDA and to report any adverse events.

### 5.2 Clinical and Regulatory Strategy

HeartWare has developed a clinical and regulatory plan designed to achieve first commercial product sales by mid 2007 in Europe and Australia, with commercial sales in the United States commencing in 2009.

HeartWare’s management has considerable expertise in regulatory affairs and the design and conduct of clinical trials. HeartWare may also engage local consulting firms specialising in heart surgery clinical trials to support clinical co-ordinators.

Before human trials can commence, HeartWare must first complete its preparatory work including formal animal trials under ‘good laboratory practice’ or GLP guidelines for submission to the regulatory bodies. These GLP animal trials are expected to commence in early 2005.

Upon completion of these preparatory steps and the receipt of regulatory approvals, Heart Ware plans to initiate a series of human trials in Australia and the EU, and then the US, as detailed in **Section 4.1** of this Prospectus.

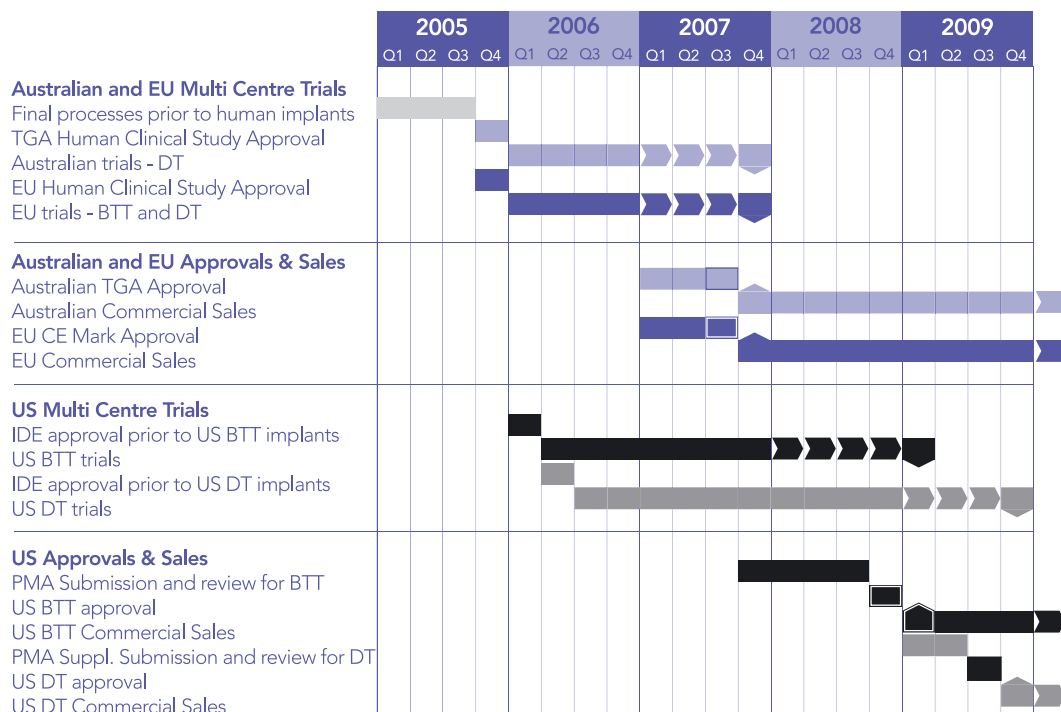
HeartWare intends to use the data from the Australian and EU human trials in order to support applications for an Investigational Device Exemption (“IDE”) for US bridge to transplant and destination therapy clinical trials .

# HeartWare expects faster recovery and hospital discharge

### 5.3 Regulatory Timeline

Set out below is HeartWare’s planned timetable for conducting its clinical trials and achieving regulatory approvals. Details of the regulatory requirements are set out in Section 5.4. HeartWare recognises that currently unforeseen circumstances might impact the envisaged timeframes for both the clinical trials and the regulatory approval process. Further details of the regulatory risks associated with HeartWare’s products and approvals are presented in Section 11.

*HeartWare’s Projected Regulatory Timeline*



### 5.4 Regulatory Requirements

The regulatory requirements currently applicable to HeartWare’s circulatory assist devices and commencement of human trials are:

#### *Australian regulations*

In Australia, the TGA is responsible for administering the Therapeutics Goods Act. The Office of Devices, Blood and Tissues is the department within the TGA responsible for devices. This Office recognises five classes of medical devices and HeartWare’s circulatory assist device falls under the category of Active Implantable Medical Devices.

The Australian Register of Therapeutic Goods (“ARTG”) controls the legal supply of therapeutic goods in Australia. The ARTG is the register of information about therapeutic goods for human use that may be imported, supplied in, or exported from Australia. Any use of an unapproved medical device in humans, even in pilot trials, requires an exemption from the requirement for inclusion on the ARTG.

In order for the Australian trials to satisfy FDA requirements, HeartWare will remain responsible for implementing the Australian trial protocol and investigational brochure, as well as maintaining clinical quality systems.

### *European Union regulations*

The EU encompasses most of the major countries in Europe, including HeartWare's principal anticipated European markets. The EU has adopted numerous directives and standards regulating the design, manufacture, clinical trials and labelling for medical devices. The European Council Medical Device Directive 93/42/EEC describes the general provisions for clinical trials and other essential requirements to support CE marking.

Devices that comply with the requirements of the Medical Device Directive ("MDD") and, for certain implantable devices such as HeartWare's HVAD, the Active Implantable Devices Directive ("AIMD"), are entitled to bear the CE mark and can be sold throughout the EU.


### *US regulations*

In the United States, medical devices are subject to review and approval by the FDA, which regulates the clinical testing, manufacture, labelling, storage, record keeping, distribution and promotion of medical devices, primarily pursuant to the requirements of the Food, Drug and Cosmetic Act and other regulatory requirements. Medical devices are classified as Class I, II or III according to risk. Devices classified as Class III, such as HeartWare's HVAD, require FDA approval of a Pre-market Approval ("PMA") application prior to commercialisation.

To obtain FDA approval to market HeartWare's products the FDA requires proof of safety and efficacy in human clinical trials performed under an IDE. An IDE application must contain pre-clinical test data supporting the safety of the product for human investigational use, information on manufacturing processes and procedures, proposed clinical protocols and other information. If the IDE application is accepted, human clinical trials may begin.

The IDE application is generally approved by the FDA for a specified number of patients and investigational sites. Clinical trials may begin once the FDA approves the IDE and the Institutional Review Board at each participating clinical site approves the trial protocol.





## 6 Intellectual Property

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HeartWare relies on a combination of patents, trade secrets and copyright, together with non-disclosure and confidentiality agreements, to establish and protect its proprietary rights in its technologies.

The Company has established an extensive patent portfolio with 14 patents issued by the US Patent and Trademark Office, and 10 international patents.

HeartWare's US and foreign issued patents and patent applications cover the fundamental technology underlying its haemodynamically and physiologically compatible full output, long term circulatory assist devices, including devices believed to be substantially smaller and more efficient than those of known competitors.

The Company actively monitors its intellectual property position, with new developments periodically reviewed to identify prudent extensions to the Company's patent portfolio.

HeartWare, Inc. has received a letter of demand from a competitor, Ventracor Limited, in respect of two of Ventracor's US patents. The Company believes that the demand has no validity and is frivolous in nature. See **Section 11.2** for more details.

The status of HeartWare's patent portfolio is included in the Patent Attorney Report set out on the following pages.



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December 14, 2004

**Re: Report on Patents and Patent Applications**

Dear Sirs and Madam:

This Report is prepared for inclusion in the Prospectus to be issued by HeartWare Limited (collectively with HeartWare, Inc., referred to as "**HeartWare**") in connection with the initial public offering of approximately 60 to 70 million new fully paid ordinary Shares at an offer price of \$0.50 per share to raise approximately, but not more than, the Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date.

The purpose of this Report is to provide specific information about HeartWare's patent portfolio.

**INTRODUCTION**

We are counsel for HeartWare in connection with all of HeartWare's intellectual property matters including, among other things HeartWare's patents and patent applications. The partner at Seyfarth Shaw LLP responsible for HeartWare's legal matters is George H. Gerstman. Mr. Gerstman has been handling HeartWare's intellectual property matters for approximately eight years, commencing in 1996 when he was intellectual property counsel for Kriton Medical, Inc., which sold all its assets including its intellectual property, to HeartWare Inc in July 2003.

Mr. Gerstman holds a Bachelor of Science in Electrical Engineering degree from the University of Illinois, a Juris Doctor degree with honors from the George Washington Law Center, and he was Assistant Patent Editor of the George Washington Law Review. He has been admitted to practice before the courts of the State of Illinois since 1964. He is also admitted to practice before various District Courts throughout the United States, various Courts of Appeals, including the United States Court of Appeals for the Federal Circuit, and the United States Supreme Court. He is registered to practice before the United States Patent and Trademark Office.

Mr. Gerstman is a former United States Patent Examiner and has over 40 years of experience as an attorney in the field of patent law. As a Patent Examiner, he examined hundreds of patent applications. As a patent attorney, he has counseled numerous medical device companies and has handled numerous patent matters for medical device companies, including Johnson and Johnson, Baxter International, St. Jude Medical, NeuroPace, Inc. and Medisystems Corporation.

In connection with HeartWare's intellectual property, Mr. Gerstman is assisted by other registered patent attorneys at Seyfarth Shaw LLP. Mr. Gerstman and the other registered patent attorneys assisting him prosecuted all of the HeartWare patent applications, including all 14 patent applications which matured to United States patents.

**PATENT PORTFOLIO**

HeartWare has taken an active role in filing and prosecuting patent applications to protect its key technologies. HeartWare and formerly Kriton Medical have filed patent applications to prevent competitors from using HeartWare’s key technology. HeartWare’s U.S. and foreign issued patents and patent applications cover the fundamental technology underlying its haemodynamically and physiologically compatible full output, long-term circulatory assist devices, including devices substantially smaller and more efficient than those of known competitors.

A list of HeartWare’s issued patents is set forth below. All maintenance fees have been paid on the issued patents when due and they are in good standing. In the United States, all issued patents are, by statute (35 U.S.C. §282), presumed valid unless under re-examination.

U.S. Patent No. 6,234,998 is presently under re-examination in the U. S. Patent and Trademark Office where this presumption does not apply. HeartWare initiated this re examination because the examiner who previously allowed the case had overlooked certain publications in the submission. Some of the original claims of this patent have been confirmed by the examiner as being allowable and HeartWare has responded to the other claims. Due to the strength of HeartWare’s other issued patents HeartWare does not consider this to be a significant issue.

Seyfarth Shaw LLP is HeartWare’s patent attorneys and have rendered a charge for the preparation of this Report.

Other than providing this Report, Seyfarth Shaw LLP has had no involvement in the preparation of this Prospectus, nor has Seyfarth Shaw LLP authorized or caused the issue of this Prospectus.

Consent for the inclusion of this Report in the Prospectus has been given in the form and context it appears. At the date of this Prospectus, consent has not been withdrawn.

**ISSUED PATENTS**

Dates are based on the US system of month, date, year

| TITLE  | COUNTRY   | PATENT NO. | STATUS          | EFFECTIVE FILING DATE (Priority Date) |
|--|-----------|------------|-----------------|---------------------------------------|
| Sealless rotary blood pump with passive magnet radial bearings & blood immersed axial bearings   | Australia | 708476     | Issued 8/5/99   | 2/20/96                               |
| Sealless rotary blood pump   | Australia | 730235     | Issued 6/14/01  | 8/13/97                               |
| Sealless rotary blood pump with passive magnetic radial bearings & blood immersed axial bearings | Australia | 734310     | Issued 6/7/01   | 2/20/96                               |
| Sealless rotary blood pump   | Australia | 742536     | Issued 4/18/02  | 8/13/97                               |
| Blood pump using cross-flow principles   | Australia | 760773     | Issued 9/11/03  | 1/19/99                               |
| Rotary blood pump with ceramic members   | Australia | 765033     | Issued 12/18/03 | 12/28/98                              |
| Active magnetic bearing system for blood pump  | Australia | 765716     | Issued 1/8/04   | 12/31/98                              |

December 14, 2004

| TITLE  | COUNTRY     | PATENT NO. | STATUS          | EFFECTIVE FILING DATE (Priority Date) |
|--|-------------|------------|-----------------|---------------------------------------|
| Sealless blood pump with means for avoiding thrombus formation                                   | Australia   | 768864     | Issued 4/22/04  | 12/23/97                              |
| Sealless rotary blood pump with passive magnetic radial bearings & blood immersed axial bearings | Israel      | 121834     | Issued 7/22/02  | 2/20/96                               |
| Sealless rotary blood pump with passive magnetic radial bearings & blood immersed axial bearings | South Korea | 351336     | Issued 8/22/02  | 2/20/96                               |
| Sealless rotary blood pump w/passive magnetic radial bearings & blood immersed axial bearings    | USA         | 5,695,471  | Issued 12/9/97  | 2/20/96                               |
| Sealless rotary blood pump   | USA         | 5,840,070  | Issued 11/24/98 | 2/20/96 and 8/13/97                   |
| Sealless rotary blood pump   | USA         | 6,080,133  | Issued 6/27/00  | 2/20/96 and 8/13/97                   |
| Sealless blood pump w/ means for avoiding thrombus formation                                     | USA         | 6,120,537  | Issued 9/19/00  | 12/23/97                              |
| Control system for an implantable heart pump   | USA         | 6,149,683  | Issued 11/21/00 | 10/5/98                               |
| Rotary blood pump with ceramic members   | USA         | 6,158,984  | Issued 12/12/00 | 12/28/98                              |
| Pump using cross-flow principles   | USA         | 6,217,541  | Issued 4/17/01  | 1/19/99                               |
| Rotary blood pump  | USA         | 6,234,772  | Issued 5/22/01  | 4/28/99                               |
| Sealless rotary blood pump   | USA         | 6,234,998  | Issued 5/22/01  | 8/13/97                               |
| Active magnetic bearing system for blood pump  | USA         | 6,264,635  | Issued 7/24/01  | 12/3/98                               |
| Sealless rotary blood pump   | USA         | 6,368,083  | Issued 4/9/02   | 8/13/97                               |
| Power system for an implantable heart pump   | USA         | 6,592,620  | Issued 7/15/03  | 10/5/98                               |
| Sealless rotary blood pump   | USA         | 6,688,861  | Issued 2/10/04  | 2/20/96 and 8/13/97                   |
| Ventricular connector  | USA         | 6,732,501  | Issued 5/11/04  | 6/26/02                               |

Sincerely yours,  
Seyfarth Shaw LLP



George H. Gerstman

# 7 Board and Management

## 7.1 Board of Directors

The Board has a broad range of experience in the medical device industry, early stage technology companies and the health industry, combined with medical, financial and commercial expertise.

### *Robert Thomas – Non Executive Chairman*



Rob Thomas has over 30 years experience in the securities industry, having recently retired as Chairman, Global Corporate & Investment Bank, Australia and New Zealand of Citigroup Global Markets Australia Pty Limited. In 1986 Rob joined County NatWest Securities Australia Limited to establish its stockbroking operations and was appointed Managing Director. This ultimately involved the acquisition of a small 30 person Sydney operation, JM Bowyer & Co., which was built up to 220 staff with operations in Melbourne, London, New York, Auckland, and Tokyo with a consistent No.1 Market Share rating in Australia during the 1990's. In April 1998, County NatWest Securities was taken over by Salomon Smith Barney and Mr Thomas was ultimately appointed Chief Executive Officer of Australia and New Zealand.

Rob is also Chairman of the Securities & Derivatives Industry Association and Deputy Chairman of Benitec Limited. He holds a Bachelor of Economics from Monash University 1963-1966 and has been a member of the Securities Institute of Australia since 1976 and was appointed a fellow to the Institute in 1997.

### *Seth Harrison M.D. – Deputy Chairman, Non Executive Director*



Dr Seth Harrison has been a life sciences venture capitalist for over 14 years and is currently the managing general partner of HeartWare's major shareholder, Apple Tree Partners, an early stage life sciences venture capital firm, based in New York, managing US\$105 million. Prior to founding Apple Tree Partners, Dr Harrison was a general partner at Oak Investment Partners, having also held positions with Sevin Rosen Funds and Nazem & Company.

Dr Harrison was previously HeartWare's Acting CEO. Dr Harrison has previously completed a number of successful investment exits, three of which were as founding investor and start-up CEO. Dr Harrison serves on the board of the International Partnership for Microbicides, a Rockefeller Foundation/Gates Foundation sponsored public-private partnerships engaged in the development of anti-HIV microbicides.

Dr Harrison holds an AB from Princeton University and an MD and MBA from Columbia University. He completed a surgery internship at the Presbyterian Hospital in the City of New York.

## 7 Board and Management

### *Stuart McConchie, Managing Director, Chief Executive Officer*



Stuart McConchie has over twenty five years international senior management experience in the medical device industry having spent more than a decade working with mechanical circulatory assist and heart failure devices.

Prior to joining HeartWare in mid 2004, Stuart consulted to a range of medical device companies in Europe, including over five years working as the European representative for Jarvik Heart Inc. during their clinical trial and regulatory programme. Stuart previously worked for 17 years with the Australian listed company, Telectronics (later Pacific Dunlop) in a range of technical, marketing and strategic roles in Melbourne, Sydney, Denver, London and Brussels. Stuart is an Australian citizen.

### *Dr Christine Bennett – Non-Executive Director*



Dr Bennett is an experienced company director, with a diverse background in clinical care, strategic planning, capital raising, advisory work and senior management in both the public and private health sectors.

Dr Bennett is Chief Executive Officer of Research Australia Limited, a national alliance of organizations promoting health and medical research. Dr Bennett has previously been a Health and Life Sciences Partner at KPMG Australia, Chief Executive Officer of Westmead Hospital (Sydney), Director of Clinical Services, South Eastern Sydney Area Health, Associate Director in the New South Wales Department of Health and a Paediatric Registrar at Prince of Wales Children's Hospital (Sydney).

Dr Bennett's other directorships include Resonance Health Limited. Dr Bennett holds a bachelor of medicine and surgery (University of Sydney), Master of Paediatrics (University of NSW) and is a Fellow of the Royal Australasian College of Physicians.

### *Dr Denis Wade, AM - Non-Executive Director*



Dr Wade has a depth of experience in the development of research based health care products in Australia and commercialisation of these technologies in the global market

Dr Wade was formerly Managing Director of Johnson & Johnson Research Pty Ltd ("J&J") from 1988-2003 and Chairman from 1989 to March 2003. For 10 years he was a member of J&J's US-based Corporate Office of Science & Technology and its Business Development Council. He was the former Foundation Professor of Clinical Pharmacology at the University of New South Wales. Dr Wade also serves on industry bodies in Australia, is a former President of the Australian Society of Clinical and Experimental Pharmacology and has held senior positions in the International Union of Pharmacology, serving as Chairman of the Clinical Pharmacology Section.

Dr Wade's other directorships include Cryptome Pharmaceuticals Limited. Dr Wade holds a bachelor of medicine and surgery, is a Fellow of the Royal Australasian College of Physicians and a Fellow of the Australian Academy of Technological Sciences and Engineering.

## 7.2 Advisory Board

The Company expects to draw on the experience and expertise of its Advisory Board which includes highly qualified professionals in the fields of cardiovascular surgery, cardiology, clinical trials, biomechanics and medical devices. The current members of HeartWare's Advisory Board are:

*O. Howard 'Bud' Frazier, MD (Chairman)*  
*(Chief Transplant Services, Director Cardiovascular Research, Texas Heart Institute)*

Dr Frazier has personally performed over 900 heart transplants and implanted almost 300 left ventricular assist devices.

For more than 25 years, Dr Frazier has been a pioneer in the surgical treatment of severe heart failure. He has been director of cardiopulmonary transplantation for 20 years. He serves on the editorial boards of several distinguished medical journals, including *Circulation*, the premier journal of the American Heart Association. He has authored or co-authored more than 1,000 scientific publications, presented over 1,200 lectures around the world, and written or edited numerous books in the field.

Dr Frazier is a former chairman of the Federal Affairs Committee for the American Society for Artificial Internal Organs and has served on other prominent committees, including the Education Committee of the American Society of Transplant Surgeons and the Advisory Board of the National Heart, Lung and Blood Institute. In 2001, he was elected president of the American Society for Artificial Internal Organs. Dr Frazier's academic appointments include Professor of Surgery at the University of Texas Health Science Center in Houston, Clinical Associate Professor of Surgery at the University of Texas M.D. Anderson Cancer Center, and Clinical Professor at Baylor College of Medicine in Houston.

*Steven W. Boyce, MD*  
*(Director of Heart Transplantation and Cardiac Assist Device Programmes, Washington Hospital Center)*

Dr Boyce has served as Director of the Cardiac Transplantation and Mechanical Circulatory Assist Device Programs for the Washington Hospital Center, as well as Director of the Cardiac Surgery Research Program for over ten years. He is certified with the American Board of Thoracic Surgery, and performs approximately 500 adult cardiac surgeries per year. Dr Boyce has been actively involved in the HeartWare LVAD program since its preliminary phases of development.

Dr Boyce's clinical research experience spans over a decade, having served as principal investigator on a number of FDA pharmaceutical and device investigational protocols. During that time, Dr Boyce has worked with a variety of mechanical circulatory support devices, both investigational and commercially available.

Dr Boyce graduated from Johns Hopkins University's undergraduate program and the University of Maryland's medical school program. He completed his residency and chief residency in general surgery at the University of California, San Francisco and then trained at UCLA in cardiothoracic surgery. Dr Boyce has a number of professional affiliations, including the International Society of Heart and Lung Transplantation, the American College of Surgeons, the Society of Thoracic Surgeons, the American College of Cardiology, the Heart Failure Society of America, and the International Society for Minimally Invasive Cardiac Surgery. Dr Boyce has published and presented on a range of topics on the surgical management of end stage heart failure.



## 7 Board and Management

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### *Leslie Miller, MD*

*(Professor of Medicine, Director Cardiovascular Division, Lillehei Heart Institute, University of Minnesota)*

Dr Miller is Professor and Director of the Cardiovascular Division and Director of the Heart Failure/Heart Transplant Program at the University of Minnesota in Minneapolis. Dr Miller has been involved in wide ranging activities in furthering advances in heart/lung transplantation.

Dr Miller is a Past President of the International Society for Heart & Lung Transplantation and the American Society of Transplant Physicians and is currently a Member of the Board of the American Heart Association. He is Founder and Chairman of the Working Group of Transplant Cardiologists and a member of the Cardiac Transplant Research Database Executive Committee. Dr Miller is also a current member on the US Federal Agency Advisory Committees for national coverage policy for the use of left ventricular assist devices and the American Heart Association Committee on Heart Failure/Transplantation.

Dr Miller has chaired a number of national and international scientific sessions on heart/lung transplantation and is principal investigator for industry and federally-sponsored clinical trials. Dr Miller has also contributed more than 285 medical papers and serves on the editorial boards and as a reviewer for major cardiovascular journals.

Dr Miller received his medical degree from the University of Missouri School of Medicine. His postgraduate training includes serving as Chief Resident in Medicine at Washington University and Barnes Hospital, Missouri, Cardiology Fellow at Peter Bent Brigham Hospital, and Senior Resident in Surgery at Boston University. Dr Miller is a Fellow of the American College of Cardiology, the American College of Chest Physicians and the American Heart Association Council on Clinical Cardiology.

### *Stephen Westaby, FRCS, MD, BSc, PhD*

*(Consultant Cardiothoracic Surgeon, John Radcliffe Hospital, Oxford, United Kingdom)*

Mr Stephen Westaby is an adult and paediatric cardiac surgeon in Oxford, United Kingdom and performs over 500 such operations per year. His main clinical interests are non transplant surgery of heart failure, surgery of the thoracic aorta and the development of new heart valve prostheses.

Mr Westaby began his medical career at the Charing Cross Hospital Medical School, University of London, having obtained degrees in biochemistry, medicine and surgery. His PhD thesis was on Bioengineering of Artificial Hearts and he is co-editor of the Journal of Congestive Heart Failure & Circulatory Support. Mr Westaby was awarded a scholarship to the Albert Einstein Medical College in New York City, has trained in general surgery at Cambridge University and took a research fellowship at the University of Alabama.

Mr Westaby was formerly Senior Registrar at Hammersmith, Great Ormond Street Hospital for Sick Children and Harefield Hospital. In 1986, Mr Westaby was appointed Chief of Cardiac Surgery for the regional Cardiothoracic Centre in Oxford.

In 1996, Mr Westaby in conjunction with colleagues from the Texas Heart Institute, USA, performed the first permanent implants of the Thermo Cardio Systems artificial heart in patients who were not eligible for heart transplantation. Mr Westaby and the Oxford Heart Centre now have an international reputation for their work on mechanical hearts and treatment of heart failure.





## 7 Board and Management

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### *Georg M. Wieselthaler, MD*

*(Clinical Director of Mechanical Circulatory Support, University of Vienna, Dept of Cardiothoracic Surgery, Vienna General Hospital)*

Dr Wieselthaler has extensive experience with numerous ventricular assist device systems and is the primary surgeon implanting the various VAD systems and supervising patient care at The University of Vienna. The University has been developing ventricular assist devices and a total artificial heart since the 1970s, and has implanted the Thoratec paracorporeal VAD and the Novacor LVAS. Dr Wieselthaler implanted the world's first MicroMed DeBakey rotary LVAD and he has since supported more than 40 patients with this pump. The University is also expected to be the second centre in the world to implant the Terumo DuraHeart, wearless centrifugal LVAD.

Currently, Dr Wieselthaler is also the Secretary General of the International Society of Rotary Blood Pumps.

### *Laman A. Gray, Jr., M.D.*

*(Professor of Surgery and Director of the Division of Thoracic and Cardiovascular Surgery at the University of Louisville School of Medicine)*

Dr Gray is highly experienced in the fields of cardiac surgery and development of artificial hearts and circulatory support systems. Dr Gray was an original investigator for the Novacor Ventricular Assist System, he performed the first clinical use of ABIOMED's SupraCor IABP and he implanted the first AbioCor Implantable Replacement Heart.

Dr Gray has been the Director of the University of Louisville School of Medicine's Division of Thoracic and Cardiovascular Surgery for more than 20 years and is a founding member of the Jewish Hospital Heart and Lung Institute and is currently the Director of the Cardiovascular Innovation Institute.

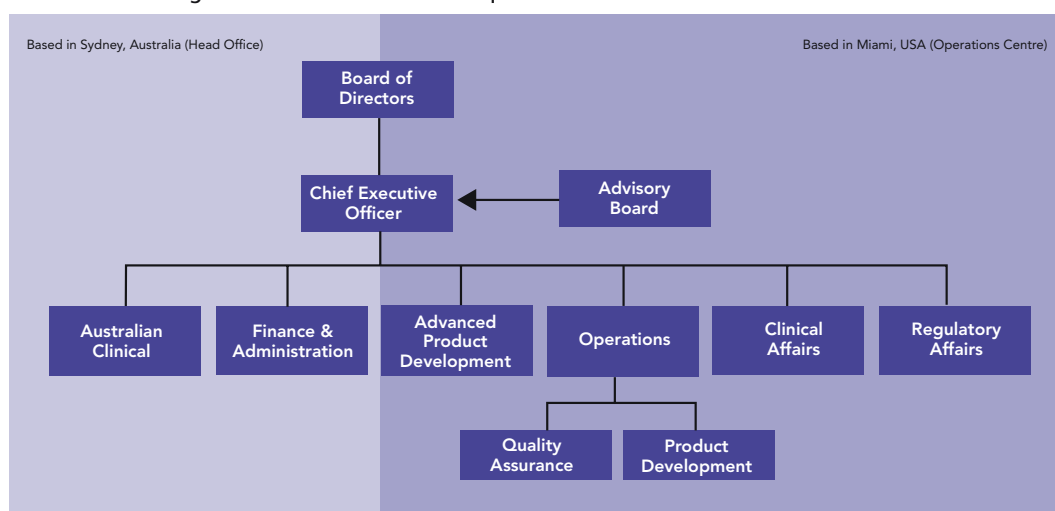
Dr Gray received his Bachelor of Arts degree with distinction in chemistry from Wesleyan University in Middletown. He then received his M.D. from Johns Hopkins University in Baltimore, and completed his training and residencies in general and thoracic surgery at the University of Michigan.

# 7 Board and Management

## 7.3 Senior Management

The Company's management team has a range and depth of relevant experience key to the Company's ability to fulfil its plans. The Company's current organisational structure is shown below.

HeartWare intends to appoint a Chief Financial Officer based in Sydney, by early 2005 with the Australian Clinical position to be filled prior to commencement of the Australian human trials. Additional management will be added as required.



The experience and background of the current senior management and advisers, who are not directors, are summarised below and in **Section 7.4**.

### *Jeffrey A. LaRose – Chief Scientific Officer*

Mr LaRose has been closely involved in the development of HeartWare's technology for seven years. He is responsible for all aspects of the design and physiological controls for HeartWare's HVAD. Mr LaRose also leads the development of HeartWare's miniaturisation technology. He has held various positions related to technology, product development and intellectual property.

Mr LaRose has 20 years experience in hydraulic technology development including roles with AEA Technology Engineering Software and Babcock and Wilcox. Mr LaRose holds a Master of Science in Mechanical Engineering.

## 7.4 Key Advisors

### *Janice T. Piasecki – Head of Regulatory Affairs*

Ms Piasecki is a regulatory expert with nearly 30 years experience, having previously worked with the Food and Drug Administration, in Boston, Massachusetts.

Prior to commencing her own regulatory consulting firm, Ms Piasecki spent 10 years at ABIOMED, Inc., in a variety of positions including Vice President, Regulatory Affairs, where she played an active role in the approval of the IDE for the AbioCor, the first totally implantable artificial heart and the PMA for the BVS 5000 Bi-Ventricular System, the first cardiac assist device approved by FDA.

Ms Piasecki holds a Bachelor of Science in Biology from Boston College and she has completed a number of FDA Training Courses. Ms Piasecki is currently a consultant to HeartWare, Inc.



## 7 Board and Management

### *Jane Reedy – Head of Clinical Affairs*

Ms Reedy has over 20 years of experience in directing clinical affairs, sales and marketing in the circulatory assist device industry. She has served as the Director of Clinical Services, Director of Sales and Director of Market Development for Thoratec Corporation in the sale of their medical devices for circulatory support and vascular graft applications. Ms Reedy has developed clinical and regulatory strategies for complex medical products, designed and directed multi-centre studies, formulated and executed global sales and marketing strategies and managed a network of distributors and clinical specialists worldwide.

Ms Reedy has a Master of Science in nursing from St. Louis University and has served as Department Head of Cardiothoracic Services at St. Louis University Hospital. Ms Reedy is currently a consultant to HeartWare, Inc.

## 7.5 Corporate Governance

### *Board of Directors and its committees*

The Board's policy is that it should include a majority of Non-Executive Directors. In addition to the Managing Director, there are currently four Non Executive Directors including the Chairman. Under the Company's constitution, Directors are elected for a period of up to three years subject to the requirement that one-third of the Directors must retire at each annual general meeting. Retiring Directors may offer themselves for re-election.

The Board of Directors is responsible for the overall corporate governance of the Company. Issues of substance affecting the Company are considered by the full Board of Directors, with advice from external advisers as required. Any conflict of interest must be provided to the Board at a board meeting as soon as practicable, and Directors may not participate in discussions or resolutions pertaining to any matter in which the Director has a material personal interest.

The Board has ultimate responsibility to the shareholders for the welfare of the Company by guiding and monitoring its business affairs. The Board delegates management of the Company's resources to the senior executive management, under the leadership of the Chief Executive Officer, to deliver the strategic plans and goals as set by the Board.

The responsibilities of the Board and the roles and division of authority between the Chairman and Chief Executive Officer will be set down in a Board Charter. In discharging their duties, Directors are provided with direct access to senior management and external advisors and auditors. Board committees and individual directors may seek, with the Chairman's approval, independent professional advice at the Company's expense for the purposes of the proper performance of their duties. The Board will implement a process to review its performance and the Board Charter annually.

The Board has reviewed the ASX Corporate Governance Council's Principles of Good Corporate Governance and Best Practice Recommendations. The recommendations cover a range of principles to promote good corporate governance. The Board is working progressively to implement these recommendations. The Board has established the Audit Committee to assist with the execution of the Board's duties and to ensure complex issues are given detailed consideration. The Board also consults with the Advisory Board in relation to technical and market issues.

The Board has not formed a Nominations Committee or Remuneration Committee as the full Board presently considers all matters relating to nomination to the Board and the remuneration of executives of the Company. The Board intends to appoint an additional independent, Non-Executive director.



## 7 Board and Management

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### *Audit Committee*

The role of the Audit Committee is to assist the Board in fulfilling its corporate governance responsibilities. The primary duties and responsibilities of the Audit Committee include recommending to the Board the appointment of the external auditors, reviewing and monitoring compliance with the audit plan of the external auditors, reviewing the Company's financial reports and monitoring the quality of financial information, monitoring the effectiveness of the accounting systems and the internal control environment, ensuring the Company has an effective risk management and compliance system, and providing a clear line of communication between the external auditors and the Board.

The Company is committed to the identification, monitoring and management of risks associated with its business activities and has established policies in relation to the implementation of practical and effective control systems.

The Committee comprises Mr Robert Thomas, Dr Christine Bennett and Mr Stuart McConchie. The Chair of the Committee is Mr Robert Thomas. Members of the Audit Committee do not receive any fee in addition to the usual Directors' fee.

### *Advisory Board*

The role of the Advisory Board is to provide the Company with an external view of its product and technology development programmes and to advise the Board upon those matters, including technology risks, new technologies, market issues and reimbursement and patient requirements.

The Advisory Board intends to meet quarterly. As part of monitoring the Company's technology risks, the Chief Executive Officer and the Board will receive copies of the minutes and any reports tabled at the Advisory Board.

The Advisory Board is currently comprised of Drs 'Bud' Frazier (Chairman), Steven Boyce, Leslie Miller, Stephen Westaby, Georg Wieselthaler and Laman Gray Jr. The CEO and Chief Scientific Officer will attend Advisory Board meetings by invitation. Members of the Advisory Board, but not the CEO and Chief Scientific Officer, will receive a fee for attendance at meetings.

### *Code of conduct*

The Company intends to adopt a formal code of conduct that requires all directors, officers and senior management and employees to observe high standards of ethics and behaviour in all of the Company's activities.

### *Continuous disclosure*

The Company is aware of the obligations that it will have under the Corporations Act and Listing Rules to keep the market fully informed of information which is not generally available and which may have an effect on the price or value of the Company's securities.

The Company intends to adopt a policy which establishes procedures to ensure that Directors and management are aware of and fulfil their obligations in relation to the timely disclosure of material price sensitive information.

All relevant information provided to the ASX will be posted immediately onto the Company's website, [www.heartwareinc.com](http://www.heartwareinc.com), in compliance with the continuous disclosure requirements of the Corporations Act and Listing Rules.

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### *Securities trading policy*

The Company intends to adopt a securities trading policy which, amongst other things, will provide that the Directors and employees of the Company may only trade the securities of the Company during certain “window periods” such as following the release of the Company’s financial results and the annual general meeting.

### *Communication to shareholders*

The Board of Directors aims to ensure that the Shareholders are informed of all major developments affecting the Company’s state of affairs. A communications policy will be developed to promote effective communications with Shareholders and encourage effective participation at general meetings. Information will be communicated to Shareholders through the Company’s annual report, annual general meeting, half-yearly results announcements and corporate website.



# 8 Independent Expert's Report

## **aoris nova** Pty Ltd

1 Central Avenue, The Australian Technology Park  
EVELEIGH NSW 1430  
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Phone: 61 2 9209 4231 Fax: 61 2 9209 4242  
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29th November 2004

The Directors,  
HeartWare Limited  
HeartWare, Inc.  
Level 1, 1 Bligh St  
SYDNEY NSW 2000

Dear Sirs,

As requested, we have prepared this independent expert's report on the technologies held and markets addressed by HeartWare Limited which will acquire the series B and common stock in HeartWare, Inc. (collectively "HeartWare" or "Company"), to be included in a prospectus dated on 17 December 2004 in connection with the Company's initial public offering of approximately 60 to 70 million new fully paid ordinary Shares at an offer price of \$0.50 per share, to raise approximately, but not more than, the Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date.

Over the past eight years HeartWare has developed an implantable heart pump, known as a Left Ventricular Assist Device (LVAD), for the treatment of congestive heart failure (CHF). This approach to treat advanced heart failure is well established both as a bridge to transplant until heart transplant can be carried out, and as a destination therapy to maintain heart pump function on a lifelong basis. However, existing products have significant drawbacks and an unacceptable failure rate, as well as the potential for a range of complications including infection, bleeding, clotting, stroke and death. HeartWare has applied a range of technological improvements to the design of a rotary LVAD with reduced complexity and increased long-term reliability.

HeartWare is currently located in Florida and after listing will have an Australian head office. The Company will carry out clinical trials in Australia as well as in Europe and USA and the CEO will reside in Australia.

### **The technology**

The essential technological advantages of HeartWare's lead product, the HVAD, are:

- The HVAD is the smallest full output device currently approaching the market and is implanted by surgical procedure involving fewer and more limited incisions and which can be completed in less than two hours
- Its small size permits implantation in the pericardial space and not in the abdomen, as with other full output pumps. Placement in the pericardium reduces operative and bleeding complications and avoids the risk of post-operative abdominal infections.
- Suitability for patients with Body Surface Area (BSA) down to 0.8m<sup>2</sup>. HeartWare intends to develop a smaller version of the HVAD to suit paediatric patients and adults with BSA less than 0.8m<sup>2</sup>.
- The use of a wide-bladed impeller containing large rare earth motor magnets that do not require high electric currents to generate their rotational effect, resulting in high electrical efficiency and minimising wires and connections. There are no other moving parts.
- An impeller suspension system that is reliable and resistant to wear, an essential for long-term implantation; it is designed to last more than 10 years.
- Use of two motors, which provide redundancy and minimise the risk of pump failure.
- Performance characteristics that provide full cardiac support.



## 8 Independent Expert's Report

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- Minimal and highly polished blood contacting surfaces with good surface washing that reduce the risk of incompatibility with the blood and consequent damage to red blood cells (haemolysis) or thrombosis.
- Minimal external connections with in-built redundancy, involving only small flexible wiring to the controller, which is fine-tuned by the clinician.

These characteristics have been combined to give a small but robust device in which reduced size and increased system efficiency have not compromised output. HVAD is not presently earning revenue but the Company expects sales to commence in two and a half years. HVAD will be followed by other devices, the MVAD and PedVAD based on the platform technologies used in the HVAD and with improved performance and characteristics intended to address different sectors of the patient population. The MVAD will be one tenth of the size of the HVAD and will form the basis for the PedVAD.

### **Development status, work program and use of funds**

HeartWare has performed extensive preclinical trials in vitro. This includes testing of the HVAD in sheep to optimise anatomical fitting, evaluate its design and pump mechanics and assess long-term compatibility with the blood. Acceptable levels of haemolysis have been demonstrated both in vitro and in vivo, and no major thrombotic events were reported during the animal trials. These trials, which involve insertion of the device for 90 days, are being finalised, and a key outcome will be to complete the preclinical trials to GLP standard during 2005 prior to human trials.

Human trials are expected to begin in Q4 2005 in Australia and Europe with the first implant in early 2006. Australia is seen as having strong expertise in heart assist devices and has a population that mirrors the areas in the world with a high incidence of CHF. Clinicians in Australia have particular experience of LVADs. HeartWare has therefore targeted Australia as a valuable place to conduct the initial trials. The clinical trials are designed to meet the requirements of the European Union for CE mark to allow marketing in Europe and a number of major markets for destination therapy (DT), as well as the US IDE requirements for continuation of the trial in the US. Subsequent US trials will study the use of the device as a bridge to transplant procedure (BTT) as a step to further trials designed to gain approval for its use as destination therapy in the US. We are not able to confirm that these trials will be carried out at these times but given satisfactory progress in animals, recruitment to clinical trials is expected to proceed as indicated and cover the requirements for registration in the major markets of Europe and the US as well as Australia.

The Company has finalised the hardware design of its controller, which is being developed in collaboration with Minnetronix Inc (St Paul, Minnesota). Minnetronix has extensive experience in the design of controllers for blood pumps and the artificial heart. The controller software is in the final stages of development. When complete, the controller software will establish the relationship between blood volume and flow and will optimise the maintenance of pulsatility. HeartWare's pump control system is intrinsically flexible and will be adapted to deliver best possible flow characteristics.

Development of HeartWare's second product, the MVAD, is approximately two years behind that of the HVAD. The Company intends to progress its development in parallel with that of PedVAD, with support from Artificial Heart Fund for the latter device. HeartWare will seek additional funding to develop the other products in its pipeline.

HeartWare, Inc. has expended approximately US\$32 million (AU\$46 million) on the development of HVAD related technologies over eight years. This can be regarded as sunk development costs. For the Company to reach the next major value indicator at the successful completion of the first insertions of HVAD into humans, and then to reach the market with HVAD and substantially advance the development of MVAD, additional funds will be required. We estimate that the funds generated by this listing will be adequate to bring the product to market provided that the milestones are met according to schedule and income is generated during clinical trials.

## Intellectual property relating to the technologies

Throughout this document the reference to HeartWare takes into account the assignment of a patent portfolio including issued patents relating to the design of the pump, its power system, connector and controller. We have not conducted an extensive patent search nor considered the Company's freedom to operate and the patent portfolio is described elsewhere in this prospectus. We have assumed that the product meets all technical requirements and milestones and that the patents taken out to cover the technology will be maintained (or awarded and maintained) and are sufficient to provide protection in the marketplace against competing products. In our opinion, HeartWare has the management capability and resources to exploit the LVAD intellectual property as planned and will continue to develop new technical advances to maintain their products in the market.

## The market

### Market size

CHF, characterised by the inability of the heart to meet the demands of the body, is a major and increasing syndrome in developed countries. In the US, hospital discharges for CHF have increased five-fold since 1970, and in the UK the direct cost of CHF to the National Health Service doubled from 1-2% of health care expenditure between 1990 and 2000. The prevalence of CHF in the US is now about 2.2% with an incidence of about 500,000 new cases annually. The annual incidence in the developed world is approximately 1.5 million cases. The lifetime risk at age 40 is 1 in 5 and increases significantly with systolic or diastolic dysfunction. Old age and a previous heart attack are the main risk factors. The direct and indirect annual cost of CHF is estimated at US\$28.8 billion. In Australia there are estimated to be 325,000 people with CHF, with 30,000 new cases annually at a total community cost of about AU\$1 billion per annum.

However, heart failure patients fall into several specific subgroups depending on both severity and cause, and therapeutic approaches differ for each subgroup. CHF is classified on the New York Heart Association scale from Class I to Class IV, with Class IV disease being the most severe. About 65% of cases are Class I and II, and a further 30% are designated Class III. Currently these patients are treated with drugs or, if their heart failure is electrical in origin, by implantation of a bi-ventricular pacemaker. It is estimated that approximately 30% of all moderate heart failure patients may be suitable for this type of electrical assistance, which re-synchronises the heart's pumping action.

Only 6-7% of CHF patients are classified as Class IV, which comprises the current market for LVADs. Because these patients have end-stage disease and a mean life expectancy of less than one year, it is appropriate to assess the market in terms of incidence rather than prevalence. In the US there are about 330,000 new cases of Class IV CHF each year, and a further 660,000 in the rest of the developed world, giving a total annual patient base of 1 million. However, not all these patients represent the market for LVADs. Some authorities estimate that because many patients would not benefit from an LVAD, or for a range of clinical reasons are not mechanical device candidates, the market for LVADs requires only about 30,000 devices per annum in the US. Other estimates put the annual market at 100,000 patients. In the developed world, therefore, the market for LVADs for Class IV CHF is in the range 90,000-300,000 devices per annum.

The market for LVADs is further divided according to the application of the device. About 3,500 patients in the US become eligible for a heart transplant annually, and 2,000-2,400 receive one. The remainder, as well as some patients who have to wait several months for a donor heart, are candidates for bridge-to-transplant use of an LVAD. There are six VADs currently approved for temporary bridge-to-transplant use in Class IV patients in Europe and three in the USA. The US market for bridge-to-transplant LVADs is about 1,000 devices annually, and the market in the developed world is three times that figure. In 2002 the US and European market for this application was worth US\$125-150 million. The bridge to transplant market is not predicted to grow between 2004 and 2008 as the organ donor supply is not expected to increase.



The use of a VAD for destination therapy in Class IV patients ineligible for transplant was first approved by the FDA in 2002, though several devices are approved for this application in Europe. Destination therapy represents most of the current market and is forecast to increase rapidly from its current low base. Estimates of the combined US and European value of this market are in the range US\$2-8 billion.

Further expansion of the market will entail the use of VADs as destination therapy for the much larger group of Class III patients, who are the main target of HeartWare's second product, the MVAD. However, it is not certain that this will occur in the immediate future and physician acceptance and reimbursement policies remain hurdles to such expansion. In the US, only Class IV patients are reimbursed for LVAD implantation.

HeartWare's product pipeline includes the PedVAD, specifically designed for paediatric patients. Eight in 1,000 newborns are diagnosed with congenital heart disease, which is the second most prevalent chronic illness in childhood. The paediatric heart failure market is not large, but is not met by existing LVADs and represents a significant niche opportunity for HeartWare.

### **Market need**

The first line of treatment for heart failure is a range of lifestyle changes combined with drug therapy that is designed to alleviate symptoms and slow progression of the condition. However, long-term drug therapy for heart failure often becomes ineffective after a time. In severe heart failure, the current therapy of choice is heart transplant, after which survival at 5 years is now about 70%. However, this is not an option for the majority of patients as there is a very limited supply of donor hearts and the selection criteria for transplant are therefore strict. The only effective therapy available to most patients in severe heart failure with a pumping disorder of the heart is mechanical assistance, and there is clear unmet need for the majority of these patients.

Nevertheless the uptake of LVADs is low. Although the FDA granted marketing approval to the market leader, Thoratec, in 1994, ten years later only 8,000 of the company's devices had been implanted in patients. The low market penetration results from significant drawbacks associated with early devices:

- Cost of the device and the related surgical methodology
- Size of the device and its effect on the patient
- The remaining high risk of sepsis and device malfunction
- Restricted quality of life of patients using the existing devices.

Despite these points, development of ventricular assist devices has advanced past a threshold of technical competence to clinical acceptance and the advances incorporated in later devices are expected to increase penetration of the market and broaden its base from bridge therapy to destination therapy. The HeartWare LVAD is an improved version of a succession of devices that have been in development for more than 20 years and used in patients since 1986. Throughout this development a number of these disadvantages have been addressed and we believe the HeartWare device is one of the most advanced.

It is estimated that, with about 1 million heart operations performed annually in the US and an equivalent amount of skill is required to insert a LVAD, there is ample infrastructure and surgical capability to accommodate the surgery for the expected number of devices entering the market. In addition, devices with the complexity of the LVAD are now well established in the market based on existing products and the range of technological advances incorporated in complex procedures used in cardiology. As more devices are used it is expected that the cost and risk will be substantially reduced.

### **Competitive environment**

HeartWare is operating in a highly competitive environment, with about forty different types of LVAD in current development by 28 companies. Two of these companies, Ventracor and Sunshine Heart, are listed on the Australian Stock Exchange, but like HeartWare, neither has yet taken a product to market. Several devices are approved for bridge-to-transplant use in the US and Europe, and for destination therapy in Europe. However, only one VAD, the Thoratec HeartMate VE, is approved for destination therapy in the US following the REMATCH trial in which 52% of patients with severe heart failure who received the LVAD were alive at 1 year compared with 25% of patients on drug therapy. In mid-2004 Thoratec was

estimated to have captured more than 90% of the US and 50% of the international VAD market, and is projecting 200 implants for destination therapy in 2004. Another first-generation LVAD, World Heart Corporation's Novacor, was approved for the Japanese market in 2002. By then it had been implanted in more than 1,300 patients, 97 of them for more than a year and one for more than 4 years.

First-generation devices are large, heavy volume displacement pumps that are likely to be quickly replaced by second- and third-generation devices with improved reliability, efficiency and patient compatibility and fewer safety issues. One company, Arrow International, recently decided to terminate development of its first-generation LionHeart LVAD to concentrate on a second-generation device. Second-generation devices employ axial flow, are generally much smaller and contain only one moving part. Devices in this group include Thoratec's HeartMate II and MicroMed Technology's DeBakey VAD, which weighs only 93 grams and has received European CE Mark for bridge-to-transplant use. Most are implanted in the abdominal cavity or intra-peritoneal space, but one, the relatively low capacity Jarvik 2000, is inserted in the left ventricle of the heart itself.

Most third-generation LVAD's, including HeartWare's HVAD are centrifugal pumps that are subjected to much less mechanical wear than axial pumps and are intrinsically more suitable for long-term destination therapy. Thoratec, Arrow, MedQuest, Berlin Heart, Terumo and Ventracor are among the companies developing third-generation pumps. One, Berlin Heart's Incor, is already approved in Europe for both bridge-to-transplant and destination therapy. This device is an axial pump and surfaces in contact with the blood are coated with heparin to reduce the risk of thrombosis.

There will also be direct competition for LVADs from alternative approaches to cardiac support, particularly in the context of expansion into the large Class III destination therapy market. For example, Sunshine Heart is developing an extra-aortic device that does not induce thrombosis through contact with the blood, and is implanted with minimal surgery. However, it has yet to be demonstrated in long-term clinical trials.

Several products competitive with HeartWare's LVADs are likely to progress to market, and market share will be determined by operational differences, time to market, surgeon and patient acceptance, price and marketing. It is argued that the HeartWare device has better performance characteristics than the competitive products. However, although HeartWare's HVAD is at the forefront of technology, it has not yet been tested in humans and until the device has entered clinical trials its true competitive edge cannot be assessed.

HeartWare has designed product packages for each patient, for the facility carrying out the implants and for facilities starting implants. All the development to date has been carried out and manufacturing will be performed in the US, which is the major world market. This proactive approach to marketing will assist in the use of the HVAD and thereby aid adoption of the device. This should allow faster approval in the US and increase clinician acceptance. The Company aims to use its clinical trials centres as training centres where the implantation procedure will be taught, and will provide 24-hour clinical support and technical assistance to its customers. HeartWare plans to sell directly into the USA, Canada, key European centres and Australia, and to develop distribution agreements for certain European countries and parts of Asia, including Japan and China. The Asian market will be developed from the Company's Sydney office.

### **The HeartWare business capability**

#### **Company resources and personnel**

The present third generation LVADs have evolved following lengthy development of earlier devices and builds on considerable experience across many implants and procedures. HeartWare has assembled a highly capable management team with experience from their previous positions in other companies and government. The CEO of HeartWare, Stuart McConchie has had a career in the development of medical devices relevant to HeartWare, specifically with Jarvik Heart Inc and previously with Teletronics. He has links to a number of key people in the industry. Jeffrey LaRose is Chief Scientific Officer and was responsible for key technical development of HVAD. Janice Piasecki, as head of regulatory affairs comes



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with considerable previous experience in the FDA and in the first approvals of an artificial heart and cardiac assist device. Jane Reedy as Head of clinical Affairs was previously Director of Clinical Services of Thoratec. Janice Piasecki and Jane Reedy are currently consultants to HeartWare.

HeartWare has attracted Directors and a Scientific Advisory Board that comprises eminent business and clinical leaders in the field, several of whom have individually carried out a significant number of operations including pioneering work to implant the earlier devices. The presence of cardiac surgeons having such experience in implanting similar devices as advisors is particularly valuable and several of them will be involved in the clinical trials of the HVAD.

### Linkages

HeartWare is developing a relationship with the Artificial Heart Fund, a UK-based charitable organisation that raises funds to develop the use of mechanical aids to the heart. The main focus of its work to date has been the Jarvik 2000 heart pump. This is a valuable relationship for the Company that will provide a range of advantages including access to the UK cardiac surgeon and patient base as assistance in obtaining European regulatory approval and reimbursement. The Company has already established linkages with hospitals in the USA, Europe and Australia that will provide the patient base for clinical trials.

### Risks

A number of general risks of the HeartWare acquisition are given elsewhere in this Prospectus. We highlight the following points:

- All research and development projects have operational and technical risk especially one with this level of complexity and intervention. The product might not fulfill its potential and operational difficulties might require modifications which will entail lengthy redevelopment and cost overruns. There is a technical risk that the product life will be shortened or the processes will not continue to fully meet expectations. We believe that this risk is moderate for the HVAD products but the time to sales/royalty income for the MVAD and other newer products has high risk
- The Company will have to develop relationships with major distributors and marketers to reach its full potential. Due to the number of other products in development there will be strong competition and attack on market share with pressure on marketing strategies. Because of its technical advantages and location in the US, HVAD should enjoy a good position.
- There is a risk that HeartWare's planned development, most particularly regulatory approvals, will take longer than scheduled. The Company has in place the collaborations required to conduct the clinical trials and has expert internal regulatory advice on which this will be based, but the outcomes of these trials is not known.
- Other technologies may reduce the competitive position of HeartWare through the release of better drugs or surgical and mechanical devices. We have not assessed the possibility of specific competing technologies taking market share from HeartWare but have considered the effects of product life cycle. There are several products in the market already and a likely new competitor is Ventracor's VentrAssist, which is expected in the market twelve months prior to the HVAD. The VentrAssist is three times the volume and twice the weight of the HeartWare HVAD.
- The LVAD device may be superseded before it reaches its full market potential. The LVAD technologies and devices have advanced considerably in the past 5 years and appear to have addressed most of the major problems of earlier devices. Due to HeartWare's IP position, another device would have to operate via a new mechanism for it to take major market share. The time to develop a new technology would give HeartWare a market advantage
- Mechanical Circulatory Support is a very active field of development and there is a risk that HeartWare could infringe one or more of its competitors' patents or that HeartWare's technology is incompletely protected by this patent portfolio. HeartWare claims a strong IP position with respect to its key technical advantages.

### Summary and conclusions

We conclude that HeartWare has technology and IP that represent valuable assets and offer advances over existing devices. The HVAD is highly competitive and the Company has management, board and advisors with the capability to bring the device to the clinic and the market and to develop products



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to meet wider markets. The markets for the LVAD devices are established and likely to grow as new devices are approved for additional indications especially for long term destination therapy and in less severe patients. There is a risk that the HeartWare LVAD devices will not meet the strict requirements of this demanding clinical market but preclinical trials have been successful and they are sufficiently well advanced in development that this may be overcome through modification and further trials. Income is expected to start in 2006 through the purchase of devices for clinical trial and commercial sales are projected to commence in 2007. Commercial risks arise through timing of development and entry into the market relative to competitors and the mitigation of this risk will be related to the capability of HeartWare's management.

### Declarations and disclosures

Aoris Nova Pty Ltd prepares technology assessments and valuations of projects and companies in life science, health and biotechnology. Both authors have experience in these industries, which are relevant to the activities of HeartWare and are registered with ASIC for the preparation of Expert Reports through a license to Aoris Nova (License Number 256684). Dr Hopper is Managing Director of Aoris Nova Pty Ltd and holds a PhD degree from the ANU, BSc from Melbourne University and Certificate of Financial Management from UTS. Dr Dawes is Senior Consultant in Aoris Nova and has a D.Phil from the University of Oxford and related business experience in technology assessments in life sciences especially in heparins and cardiac insufficiency.

We have sourced information from HeartWare and independent reports and publications from on-line databases and libraries. All comments, forecasts and recommendations made in this report are made in good faith on the basis of information available at the time. Aoris Nova does not guarantee that the conclusions drawn in this report will actually occur because of possible changes in the markets and business environment, which are outside our control to know. Aoris Nova has also not sought to verify all of the publicly available information used. We have not assessed the legal status of any agreements or patents nor audited any financial forecasts of HeartWare. Any particular commercial arrangements enjoyed with other organizations are assumed to continue. A draft report was issued to the due diligence committee of HeartWare to confirm factual accuracy and some changes were made to reflect these. We do not make recommendations on the purchase of Shares in HeartWare.

This report is provided exclusively for the Prospectus dated on 17 December 2004 and shall not be used for any other purpose without written permission. We consent to the issue of this report in this form and context. We have not otherwise been involved in the preparation or the issue of this Prospectus and specifically disclaim liability in respect of any statements included elsewhere in it. Aoris Nova has acted independently in preparing this report and neither its Directors nor staff has any pecuniary or other interest in any of the entities or their associates that could reasonably be regarded as affecting its ability to give an unbiased opinion. Aoris Nova will receive normal professional fees for the preparation of this report and with the exception of these fees, will not receive any other direct or indirect benefits.

Yours faithfully,

### AORIS NOVA PTY LTD



Kelvin Hopper PhD  
Managing Director



Joan Dawes D.Phil  
Senior Consultant



## 9 Financial Summary

### 9.1 Introduction

The financial information set out below comprises a pro-forma consolidated historical balance sheet as at 30 September 2004. This financial information has been compiled from the accounts of HeartWare being a newly incorporated entity in November 2004 with 2,000 Shares at \$0.50 per Share called HeartWare Limited, audited accounts of HeartWare, Inc. for the year ended 31 December 2003 and the accounts for the 9 months ended 30 September 2004 as described in **Section 9.3**.

No historical statements of financial performance or statements of cash flows have been included in this Prospectus as HeartWare is a non-trading investment holding company incorporated specifically for the acquisition of HeartWare, Inc. The accounts of HeartWare, Inc. for the period ended 31 December 2003 and the 9 months ended 30 September 2004 have been restated to comply with the measurement and recognition principles of Australian Equivalent International Financial Reporting Standards (“**AEIFRS**”) and other mandatory professional reporting requirements in Australia. AEIFRS are consistent with International Financial Reporting Standards (“**IFRS**”).

Although the pro-forma consolidated financial position has been prepared as at 30 September 2004 for illustrative purposes, the Company’s first full reporting period will be subsequent to 1 January 2005, ending 31 December 2005. Accordingly, the first financial report will be subject to compliance with AEIFRS, as issued by the Australian Accounting Standards Board. Therefore, all financial information and related accounting policies included in this Prospectus is in accordance with AEIFRS.

In certain circumstances AEIFRS is different to the Generally Accepted Accounting Principles of the United States (“**US GAAP**”) accounting policies and the standards, which have been applied to HeartWare, Inc. for those periods. A summary of the adjustments made to the US GAAP accounts for HeartWare, Inc. is set out in **Section 9.3.2**.

The information set out in **Section 9** should be read in conjunction with the Independent Accountant’s Report prepared by Grant Thornton Corporate (NSW) Pty Limited set out in **Section 10** and the risk factors set out in **Section 11**.

### 9.2 Acquisition of Interests in HeartWare, Inc.

HeartWare, Inc. was incorporated in Delaware, USA on 8 April 2003 as Perpetual Medical, Inc., and changed its name to HeartWare, Inc. on 10 July 2003. On 11 July 2003, HeartWare, Inc. completed the acquisition of the assets from Kriton Medical, Inc., which included the HeartWare technology, patents, plant and equipment and assumption of employee entitlements and other liabilities. Over the last 8 years, approximately \$46 million (US\$32 million) has been invested and committed to developing HeartWare’s proprietary technology, establishing its manufacturability and conducting animal trials.

Simultaneously with the closing of the Offer under this Prospectus and the US Private Placement, the Company will acquire not less than 98.87% of the Series B stock on issue by HeartWare, Inc., (the “**Acquisition**” (no common stock had been issued)). The common stock and Series B stock are the only voting stock and the Series B stock is the only stock entitled to receive dividends if dividends are declared on the common stock. Immediately prior to completion of the Acquisition, Apple Tree Partners will convert its Notes on issue to HeartWare, Inc., into Series B stock.

The purchase consideration for the Acquisition is \$44.0 million, payable in Shares in the Company at \$0.50 per Share, immediately after and conditional upon the closing of the Offer. The total conversion of the Notes into Series B Stock is 1,208,465 Series B Shares, regardless of the face value of the Notes. From October 2003, Apple Tree Partners has invested and has committed to invest not less than US\$11.60 million of Note funding to HeartWare, Inc. up until completion of the Acquisition or 31 January 2005, whichever is earlier.

HeartWare, Inc.'s authorised capital consists of Series A-1 Non-Voting Preferred Stock ("**Series A-1 Stock**"), Series A-2 Non-Voting Preferred Stock ("**Series A-2 Stock**"), Series B Convertible Participating Preferred Stock ("**Series B Stock**") and Common Stock ("**Common Stock**"). Series A-1 Stock has a US\$10 per share junior liquidation preference and is not convertible. Series A-2 Stock has a US\$21 per share junior liquidation preference and is not convertible. HeartWare, Inc. currently has outstanding:

- 626,652 Shares of Series A-1 Stock; 18,000 owned by Apple Tree Partners and 608,652 owned by certain former holders of Shares of preferred stock of Kriton Medical, Inc., the predecessor of the HeartWare, Inc. business.
- 436,443 Shares of Series A-2 Stock; 1,200 owned by Apple Tree Partners and 435,243 owned by certain former holders of Shares of preferred stock of Kriton Medical, Inc.
- 603,130 Shares of Series B Stock; 582,610 owned by Apple Tree Partners and 20,520 owned by the Kriton Medical Angel Investors.

The minority interest relating to the Series A-1 and Series A-2 Stock and the Series B Stock in HeartWare, Inc. is set out in **Section 9.3.6** and **Section 9.3.7**.

### 9.3 Pro-Forma Statement of Consolidated Financial Position

The Pro-forma Consolidated Balance Sheet as at 30 September 2004 has been compiled from the accounts of HeartWare adjusted as described in **Section 9.1** to reflect the intended structure and operations of HeartWare following completion of the Acquisition, the Offer as set out in this Prospectus and the US Private Placement.

In order to understand the basis of preparation, assumptions and limitations underlying the Pro-Forma Consolidated Balance Sheet as at 30 September 2004, the historical financial information presented in this Prospectus should be read in conjunction with:

- the Summary of Significant Accounting Policies set out in **Section 9.3.2**;
- the risk factors described in **Section 11**;
- the Independent Accountant's Report on Historical Financial Information set out in **Section 10**; and
- other information contained in this Prospectus.

Any reference to the accounts of HeartWare, Inc. for the year ended 31 December 2003 is a reference to the accounts of HeartWare, Inc., which were audited by Grant Thornton LLP in accordance with auditing standards generally accepted in the United States of America who issued an unqualified audit opinion with an explanatory paragraph relating to the Company's ability to continue as a going concern. Any reference to the unaudited accounts of HeartWare, Inc. for the 9 months ended 30 September 2004 is a reference to the accounts of HeartWare, Inc. which were reviewed by Grant Thornton LLP in accordance with Statements and Standards for Accounting and Review Services issued by the American Institute of Certified Public Accountants.

These accounts have been subject to certain pro-forma adjustments set out in **Section 9.3.1**. The pro-forma adjustments include the restatement of these accounts in accordance with AEIFRS and the translation of these accounts into Australian dollars.

The Pro-forma Consolidated Balance Sheet as at 30 September 2004 reflecting the net asset position of the Company immediately before and after completion of the Acquisition and Offer is set out below. The Pro-forma Consolidated Balance Sheet has been prepared in accordance with AEIFRS.



## 9 Financial Summary

|                                      | Note  | Company <sup>1</sup><br>30-Sep-2004<br>\$000 | Reviewed<br>HWI <sup>2,3</sup><br>30-Sep-2004<br>\$000 | Consolidation<br>and Pro-forma<br>Adjustments <sup>4</sup><br>\$000 | Pro-forma<br>30-Sep-2004<br>\$000 |
|--------------------------------------|-------|--|--|---|-----------------------------------|
| <b>Current assets</b>                |       |  |  |   |                                   |
| Cash and cash equivalents            | 9.3.3 | 1  | 428  | 32,000  | 32,429                            |
| <b>Total current assets</b>          |       | <b>1</b>                                     | <b>428</b>   | <b>32,000</b>   | <b>32,429</b>                     |
| <b>Non-current assets</b>            |       |  |  |   |                                   |
| Property, plant and equipment        |       | -  | 309  | -   | 309                               |
| Goodwill                             | 9.3.4 | -  | -  | 35,796  | 35,796                            |
| Other Intangible assets              | 9.3.5 | -  | 10,013   | -   | 10,013                            |
| Other non-current assets             |       | -  | 30   | -   | 30                                |
| <b>Total Non-Current Assets</b>      |       | <b>-</b>                                     | <b>10,352</b>  | <b>35,796</b>   | <b>46,148</b>                     |
| <b>Total Assets</b>                  |       | <b>1</b>                                     | <b>10,780</b>  | <b>67,796</b>   | <b>78,577</b>                     |
| <b>Current liabilities</b>           |       |  |  |   |                                   |
| Trade and other payables             |       | -  | (1,762)  | 896   | (866)                             |
| Short-term borrowings                |       | -  | (12,712)   | 12,712  | -                                 |
| <b>Total current liabilities</b>     |       | <b>-</b>                                     | <b>(14,474)</b>  | <b>13,608</b>   | <b>(866)</b>                      |
| <b>Non-current liabilities</b>       |       |  |  |   |                                   |
| Trade and other payables             |       | -  | (229)  | -   | (229)                             |
| Long-term borrowings                 |       | -  | -  | (1,420)   | (1,420)                           |
| <b>Total non-current liabilities</b> |       | <b>-</b>                                     | <b>(229)</b>   | <b>(1,420)</b>  | <b>(1,649)</b>                    |
| <b>Total liabilities</b>             |       | <b>-</b>                                     | <b>(14,703)</b>  | <b>12,188</b>   | <b>(2,515)</b>                    |
| <b>Net assets</b>                    |       | <b>1</b>                                     | <b>(3,923)</b>   | <b>79,984</b>   | <b>76,062</b>                     |
| <b>Shareholders' equity</b>          |       |  |  |   |                                   |
| Share Capital                        | 9.3.6 | 1  | 75   | 75,925  | 76,001                            |
| Retained earnings                    |       | -  | (3,998)  | 3,998   | -                                 |
| <b>Parent equity interest</b>        |       | <b>1</b>                                     | <b>(3,923)</b>   | <b>79,923</b>   | <b>76,001</b>                     |
| Minority interest                    | 9.3.7 | -  | -  | 61  | 61                                |
| <b>Total Shareholders' equity</b>    |       | <b>1</b>                                     | <b>(3,923)</b>   | <b>79,984</b>   | <b>76,062</b>                     |

(1) Represents the Pro-forma Balance Sheet of the Company as at 30 September 2004

(2) Represents the adjusted Balance Sheet of HeartWare Inc as at 30 September 2004

(3) The financial position of HeartWare, Inc. has assumed an exchange rate of A\$1 to US\$0.70

(4) Pro-forma adjustments are set out in more detail in Section 9.3.1

### 9.3.1 Pro-forma adjustments

The Pro-forma Consolidated Balance Sheet of HeartWare has been prepared on the basis that the following transactions have been effected as at 30 September 2004:

- i) conversion of the Notes (classified as HeartWare, Inc. short-term borrowings) into 1,208,465 Series B Shares in HeartWare, Inc.
- ii) completion of the Acquisition of not less than 1,791,075 or 98.87% of the Series B Preferred Stock in the capital of HeartWare, Inc. for a total consideration of A\$44.0 million. The total consideration will be payable to Apple Tree Partners (and the other shareholders) by the issue of 88.0 million Shares in the Company at a price of \$0.50 each
- iii) in accordance with the Exchange Agreement, the issue of \$1.42 million in convertible notes to Apple Tree Partners. The terms and conditions are set out in **Section 12.5**.
- iv) completion of the Offer and the US Private Placement, of up to \$35.0 million and the subscription of up to 70.0 million Shares at \$0.50 each, at the Upper Target Subscription, subject to the conditions set out in **Section 1.12** and **Section 12**.
- v) payment of expenses associated with the Offer and the US Private Placement of approximately \$3.0 million, which have been charged against equity
- vi) restatement of the non-current Intangible Assets from US GAAP, in accordance with AEIFRS in respect to capitalised Research and Development Expenditure

### 9.3.2 Summary of significant accounting policies

#### *Basis of Accounting*

The financial information included in this Prospectus has been compiled from the accounts of the Company and HeartWare, Inc., which have been prepared in accordance with the requirements of the Corporations Act, applicable Australian Accounting Standards, AEIFRS, Urgent Issues Group Consensus Views and generally accepted accounting principles for the presentation of financial information for inclusion in a prospectus in Australia. As set out below and in **Note 9.3.5**, these accounts include certain AEIFRS adjustments to the HeartWare, Inc. accounts, which were prepared on US GAAP accounting policies.

These accounts have been prepared on an accruals basis and are based on historical costs and do not take into account changing money values or, except where stated, current valuations of non current assets. Cost is based on the fair values of the consideration given in exchange for assets. The accounting policies have been consistently applied, unless otherwise stated.

Set out below are the relevant extracts of the significant accounting policies adopted in the preparation of the financial information included in this Prospectus.

#### *Australian Equivalent International Financial Reporting Standards*

As noted in **Section 9.1** above, the financial information has been prepared in accordance with IFRS by virtue of compliance with AEIFRS. For financial reporting periods beginning on or after 1 January 2005, the Company must comply with AEIFRS as issued by the Australian Accounting Standards Board.



HeartWare, Inc. historical financial information was prepared in accordance with US GAAP. The differences between AEIFRS and US GAAP required a restatement of the Intangible Assets set out in **Section 9.3.5**. We have set out the differences, where appropriate, between AEIFRS and US GAAP in the respective accounting policy notes below.

The Directors have not quantified the effects of the differences discussed below in relation to the future financial performance of the Company, as the Company has provided no forecasts. Accordingly, there can be no assurances that the financial performance and financial position of HeartWare as disclosed in this Prospectus will not be significantly different determined in accordance with AEIFRS (versus US GAAP) accounting policies.

### *a) Principles of consolidation*

The consolidated accounts incorporate the assets and liabilities of all entities controlled by the Company as at 30 September 2004 and the results of all controlled entities for the period then ended. HeartWare and its controlled entities together are referred to in this Prospectus as the Consolidated Entity. The effects of all transactions between entities in the consolidated entity are eliminated in full. Minority interests in the results and equity of controlled entities are shown separately in the consolidated Income Statement and Balance Sheet, respectively.

Where control of an entity is obtained during a financial year, its results are included in the consolidated Income Statement from the date on which control commences. Where control of an entity ceases during a financial year its results are included for that part of the year during which control existed.

Where necessary, dissimilar accounting policies adopted by controlled entities have been amended to ensure consistent policies are adopted within the consolidated entity.

### *b) Going concern*

The financial statements have been prepared on a going concern basis, which anticipates the ability of the company to meet its obligations in the normal course of business. The ability of the Company to meet its existing obligations and those relating to recent acquisitions (as detailed in the Prospectus) will depend on the Company's ability to raise funds pursuant to the Prospectus, and raise further funds through the issue of additional share capital to meet future development and commercialisation commitments, as and when required. As reflected in **Section 1.3 'Use of Funds'**, the Directors have made relevant allowances for working capital, research and development payments and commitments based on the disclosures set out in this Prospectus.

### *c) Taxation*

Deferred income tax is provided, using the liability method, on all temporary differences at the balance sheet date between the tax bases of assets and liabilities and their carrying amounts for financial reporting purposes.

Deferred income tax liabilities are recognised for all taxable temporary differences:

- i) except where the deferred income tax liability arises from goodwill amortisation or the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affects neither the accounting profit nor taxable profit or loss.
- ii) in respect of taxable temporary differences associated with investment in subsidiaries, associates and interests in joint ventures, except where the timing and the reversal of the temporary difference can be controlled and it is probably that the temporary difference will not reverse in the foreseeable future.

Deferred income tax assets are recognised for all deductible temporary differences, carry-forward of unused tax assets and unused tax losses, to the extent that it is probable that taxable profit will be available against which the deductible temporary differences, carry-forward of unused tax assets and unused tax losses can be utilised:

- i) except where the deferred income tax asset relating to the deductible temporary difference arises from the initial recognition of an asset or liability in a transaction that is not a business combination and, at the time of the transaction, affect neither the accounting profit nor taxable profit or loss; and
- ii) in respect of deductible temporary differences associated with investments in subsidiaries, associates and interests in joint ventures, deferred tax assets are only recognised to the extent that it is probable that the temporary differences will reverse in the foreseeable future and taxable profit will be available against which the temporary difference can be utilised.

The carrying amount of deferred income tax assets is reviewed at each balance sheet date and reduced to the extent that it is no longer probable that sufficient taxable profit will be available to allow all or part of the deferred income tax asset to be utilised.

Deferred income tax assets and liability are measured at the tax rates that are expected to apply to the period when the asset is realised or the liability is settled, based on tax rate (and tax laws) that have been enacted or substantively enacted at the balance sheet date.

#### *d) Share based payments*

All employee services received in exchange for the grant of any share-based compensation are measured at their fair values. These are indirectly determined by reference to the stock options awarded. Their value is appraised at the grant date, excluding the impact of any non-market vesting conditions (for example, profitability and sales growth targets).

All share-based compensation is ultimately recognised as an “Employee compensation and benefit expense” with a corresponding credit to additional paid-in capital, net of deferred tax where applicable. If vesting periods or other vesting conditions applies, the expense is allocated over the vesting period, based on the best available estimate of the number of stock options expected to vest. Non-market vesting conditions are included in assumptions about the number of options that are expected to become exercisable. Estimates are subsequently revised, if there is any indication that the number of stock options expected to vest differs from previous estimates. However, no adjustment to expense recognised in prior periods is made if fewer stock options ultimately are exercised than originally estimated.

Upon exercise of stock options, the proceeds received net of any directly attributable transaction costs are reallocated to share capital (nominal value) and additional paid-in capital.

Shares on a public equity market or other performance targets established by the Directors or set out in the employee share option scheme is summarised in **Section 12.5**.

Under US GAAP, employee share options may be accounted by the following ways:

- i) expense recognition similar to AASB 2; or
- ii) expense recognition based on the intrinsic value at grant date (which is usually zero).

Reliable estimation of the differences between AEIFRS and US GAAP accounting policies is impracticable as the details for future equity based remuneration plans dependent on the future performance of the Company's Shares at the time of such share based payments.

### *e) Acquisition of assets*

The purchase method of accounting is used for all acquisitions of assets regardless of whether equity instruments or other assets are acquired. Cost is measured as the fair value of the assets given up, share issued or liabilities undertaken at the date of acquisition plus incidental costs directly attributable to the acquisition. Where equity instruments are issued in an acquisition, the value of the instruments is their market price as at the acquisition date, unless the notional price at which they could be placed in the market is a better indication of fair value. Transaction costs arising on the issue of equity instruments are recognised directly in equity.

Goodwill is brought to account on the basis described in note (f).

Where an entity or operation is acquired and the fair value of the identifiable net assets acquired, including any liability for restructuring costs, exceeds the cost of acquisition, the difference, representing a discount on acquisition, is accounted for by reducing proportionately the fair values of the non-monetary assets acquired until the discount is eliminated. Where, after reducing to zero the recorded amounts of the non-monetary assets acquired, a discount balance remains, it is recognised as revenue in the Income Statement.

### *f) Intangible assets*

- i) **Goodwill** – Where an entity or operation is acquired, the identifiable net assets acquired are measured at fair value. The excess of the fair value of the cost of acquisition over the fair value of the identifiable net assets acquired, including any liability for restructuring costs, is brought to account as goodwill. Goodwill is not amortised under AEIFRS but subjected to an annual impairment test based on impairment indicators. An impairment loss must be recognised in the Income Statement when an assets carrying amount exceeds its recoverable amount. Assets classified as 'held for disposal' must be measured at the lower of the carrying amount of the fair value less selling costs. AEIFRS requires a reversal of impairment losses when there has been a change in economic conditions or in the expected use of the asset.
- ii) **Research and development** – Research costs are expensed as incurred. Development expenditure incurred on an individual project is carried forward when its future recoverability can reasonably be regarded as assured. Any expenditure carried forward is amortised over the period of expected future sales from the related project.

The carrying value of development costs is reviewed for impairment annually when the asset is not yet in use, and otherwise when events or changes in circumstances indicate that the carrying value may not be recoverable.

AASB 138 '*Intangible Assets*' requires development costs be capitalised only after six specific criteria have been met. These criteria include requirements specific to the Company such as:

- a. the technical and commercial feasibility of the asset in use is required to have been established along with a commercially viable market (i.e. there must be an intention to be able to complete the intangible asset and either use it or sell it and demonstrate how the asset will generate future economic benefits)
- b. the expenditure attributable to the intangible asset during its development is required to have been measured reliably. AASB 138 prohibits the recognition of intangible assets arising from research activities or the research phase of an internal project

HeartWare, Inc. has not capitalised its research and development expenditure historically, which is in accordance with US GAAP. US GAAP requires the Company to expense all of its research and development expenditure in the year that it was incurred. HeartWare, Inc. has not capitalised the costs associated with obtaining patents. These are expensed in the year that they are incurred. The restatement of these accounts is set out in **Section 9.3.5**.

### *g) Foreign exchange contracts*

Financial instruments, including derivatives, are recognised on the balance sheet when the entity becomes party to the enforceable provisions of the instrument. Derivatives, whether assets or liabilities, are considered held for trading, except where they are qualifying hedging instruments.

Changes in the fair value of assets and liabilities classified as 'held at fair value through profit and loss' are recognised as gains or losses in the income statement. Changes in the fair value of available-for-sale assets, other than impairment losses and foreign exchange gains and losses are recognised directly in equity. Dividends and interest revenue are recognised as revenue in the income statements.

Investments in equity instruments that are not quoted in an active market and whose fair values cannot be reliably measured, and derivatives linked to and settled by such instruments are measured at cost.

### *h) Foreign currency translation*

i) **Transaction** – Transactions in foreign currencies are recorded at the rate ruling at the date of the transaction. Monetary assets and liabilities denominated in foreign currencies are retranslated at the rate of exchange ruling at the balance sheet date. All differences are taken to the income statement with the exception of differences on foreign currency borrowings that provide a hedge against a net investment in a foreign entity. These are taken directly to equity until the disposal of the net investment, at which time they are recognised in the income statement. Tax charges and credits attributable to exchange differences on those borrowings are also dealt with in equity.

ii) **Foreign controlled entity** – The assets and liabilities of overseas subsidiaries are translated at the rate of exchange ruling at the balance sheet date. The income statements of overseas subsidiaries are translated at weighted average exchange rates for the year. The exchange differences arising on the retranslation are taken directly to equity.

Upon the disposal or partial disposal of a foreign entity, accumulated exchange differences are recognised in the income statement as a component of the gain or loss on disposal.

Goodwill and fair value adjustments arising on the acquisition of a foreign entity are treated as assets and liabilities of the acquiring company and are recorded at the exchange rate at the date of transaction.

iii) **Pro-forma foreign currency translation** – The pro-forma financial information, included in this Prospectus, was consolidated and gave effect to the acquisition of HeartWare, Inc., which was translated at an assumed exchange rate of A\$1 to US\$0.70. The completion of the Acquisition and Offer will occur at some time after this date, and therefore, the prevailing currency exchange rate at that time may be materially lower or higher at that time. This will impact the Consolidated Balance Sheet of the Company as reported in Australian dollars.

### 9.3.3 Cash and cash equivalents

The pro-forma consolidated cash and cash equivalents position based on the Upper Target Subscription of \$35 million has been calculated as follows:

|   | As at<br>30-Sep-2004<br>\$000 |
|---|-------------------------------|
| Opening cash and cash equivalents balance   | 1                             |
| Cash and cash equivalents acquired – HeartWare, Inc.                                      | 428                           |
| <b>Pro-forma adjustments</b>  |                               |
| Proceeds from the Offer and the US Private Placement                                      | 35,000                        |
| Costs incurred in connection with the Offer and the US Private Placement                  | (3,000)                       |
| <b>Pro-forma consolidated cash and cash equivalents position at<br/>30 September 2004</b> | <b>32,429</b>                 |

The pro-forma consolidated cash and cash equivalents position in the Pro-forma Consolidated Balance Sheet has been arrived at after adjusting for the impact of:

- Cash and cash equivalents acquired in connection with the Acquisition of HeartWare, Inc.
- The receipt of proceeds from the Offer amounting to \$35.0 million in relation to a subscription of 70.0 million fully paid ordinary Shares at an issue price of \$0.50 per New Share.
- The payment of expenses of the Offer and the US Private Placement, as outlined in the Prospectus, estimated at \$3.0 million

### 9.3.4 Goodwill

|  | As at<br>30-Sep-2004<br>\$000 |
|--|-------------------------------|
| Opening goodwill balance                       | -                             |
| <b>Consolidation adjustments</b>               |                               |
| Goodwill on consolidation                      | 35,797                        |
| <b>Pro-forma goodwill at 30 September 2004</b> | <b>35,797</b>                 |

The pro-forma consolidated goodwill in the Pro-forma Consolidated Balance Sheet has been arrived at after adjusting for the impact of goodwill on consolidation in accordance with AASB 138 'Intangible Assets' being the \$44.0 million in consideration for the Acquisition less the shareholder's equity of HeartWare, Inc. of \$9.7 million (post pro-forma adjustment to convert Notes to Series B stock in HeartWare, Inc.) and the issue of \$1.42 million in convertible notes in accordance with the Exchange Agreement.

## 9.3.5 Other intangible assets

|   | As at<br>30-Sep-2004<br>\$000 |
|---|-------------------------------|
| Opening other intangible assets balance                         | -                             |
| Research and Development expenditure acquired – HeartWare, Inc. | 10,013                        |
| <b>Pro-forma intangible other assets at 30 September 2004</b>   | <b>10,013</b>                 |

The pro-forma consolidated intangible assets in the Pro-forma Consolidated Balance Sheet has been arrived at after adjusting for the impact of intangible assets acquired in connection with the Acquisition of HeartWare, Inc. restated in accordance with AASB 138 'Intangible Assets'. This has resulted in an adjustment to Research and Development Expenditure of \$10.0 million when compared to the historical application of US GAAP.

## 9.3.6 Share Capital

The pro-forma consolidated share capital has been calculated as follows:

|   | As at<br>30-Sep-2004<br>\$000 | No. of Shares<br>'000 |
|---|-------------------------------|-----------------------|
| Opening share capital   | 1                             | 2                     |
| <b>Pro-forma adjustments</b>  |                               |                       |
| Shares issued as consideration for the Acquisition of HeartWare, Inc. | 44,000                        | 88,000                |
| Proceeds from the Offer and the US Private Placement                  | 35,000                        | 70,000                |
| Costs associated with the Offer and the US Private Placement          | (3,000)                       | -                     |
| <b>Pro-forma share capital at 30 September 2004</b>                   | <b>76,001</b>                 | <b>158,002</b>        |

The share capital in the Pro-forma Consolidated Balance Sheet has been calculated after adjusting for the impact of:

- The issue of 88.0 million Shares at an issue price of \$0.50 per share amounting to \$44.0 million, which represents the Shares issued as consideration for the acquisition of HeartWare, Inc. as outlined in this Prospectus.
- The issue of up to 70.0 million Shares at an issue price of \$0.50 per share amounting to up to \$35.0 million, which represents the proposed amount to be raised under this Offer as outlined in this Prospectus and the US Private Placement.
- The payment of expenses of the Offer and the US Private Placement as outlined in this Prospectus estimated at \$3.0 million.

## 9.3.7 Minority interests

The pro-forma minority interest has been calculated as follows:

|   | As at 30-Sep-2004<br>\$000 |
|---|----------------------------|
| <b>Minority interest comprises</b>                      |                            |
| Share capital   | 86                         |
| Reserves  | -                          |
| Retained profits/losses                                 | (25)                       |
| <b>Pro-forma minority interest at 30 September 2004</b> | <b>61</b>                  |

The minority interest relates to minority interests in the capital classes of HeartWare, Inc., as set out in **Section 9.2** and **Section 12.2**.

## 9.4 Equity Structure

### *Share structure following completion*

Shares on issue by the Company following completion of the Acquisition and the Offer is as follows:

| At the Lower Target Subscription:          |                 |                        |                         |                    |                  |
|--|-----------------|------------------------|-------------------------|--------------------|------------------|
| Holder                                     | Opening Balance | Issued for Acquisition | Issued under this Offer | Final Total        | % of Final Total |
| <b>Number of Shares</b>                    |                 |                        |                         |                    |                  |
| Apple Tree Partners                        | 2,000           | 87,003,221             | -                       | 87,005,221         | 58.79            |
| Other HeartWare, Inc. holders              | -               | 996,779                | -                       | 996,779            | 0.67             |
| New Investors under the Offer <sup>1</sup> | -               | -                      | 60,000,000              | 60,000,000         | 40.54            |
| <b>Total</b>                               | <b>2,000</b>    | <b>88,000,000</b>      | <b>60,000,000</b>       | <b>148,002,000</b> | <b>100.00%</b>   |

| At the Upper Target Subscription:          |                 |                        |                         |                    |                  |
|--|-----------------|------------------------|-------------------------|--------------------|------------------|
| Holder                                     | Opening Balance | Issued for Acquisition | Issued under this Offer | Final Total        | % of Final Total |
| <b>Number of Shares</b>                    |                 |                        |                         |                    |                  |
| Apple Tree Partners                        | 2,000           | 87,003,221             | -                       | 87,005,221         | 55.07            |
| Other HeartWare, Inc. holders              | -               | 996,779                | -                       | 996,779            | 0.63             |
| New Investors under the Offer <sup>1</sup> | -               | -                      | 70,000,000              | 70,000,000         | 44.30            |
| <b>Total</b>                               | <b>2,000</b>    | <b>88,000,000</b>      | <b>70,000,000</b>       | <b>158,002,000</b> | <b>100.00%</b>   |

<sup>1</sup> This includes 10.0 million Shares to be acquired by Apple Tree Partners and other "accredited investors" under the US Private Placement as described in **Section 12** of this Prospectus.

We note the equity structure above does not give effect to any pro-forma impact, which may result from the exercise of Apple Tree Partners' convertible notes of \$1.42 million. The conversion of these notes is subject to certain performance hurdles and other conditions summarised in **Section 12.5**.

## Options to be issued and Total Option Structure

The Options to be issued or agreed to be issued by the Company, on or before completion of the Offer, are as follows:

| Options   | Holders  | Number  | Exercise Price      | Expiry Date           | Other Terms  |
|---|--|---|---------------------|-----------------------|--|
| <b>Employee Share Option Plan</b>                                     | Eligible Employees of HeartWare and its subsidiary HeartWare, Inc. | Up to 10% of the Company's Issued Capital                     | As set by the Board | Five years from Issue | As set out in the Employee Share option Plan as summarised in <b>Section 12.5</b> .<br><br>At the date of Listing, the Company expects to have issued 11,044,685 Options under the ESOP to existing employees, of which 3,355,000 Options will be vested in accordance with the Rules of the ESOP. |
|   |  | <b>11,044,685</b><br>(Assuming the Upper Target Subscription) |                     |                       |  |
| <b>Fine Options</b>   | Dr R Fine  | 3% of the Company's Issued Capital (fully diluted)            | \$0.20              | 90 days from Issue    | The terms of these Options are summarised in <b>Section 12.5</b> .<br><br>Apple Tree Partners has an option to acquire one third of these options for US\$500,000.<br><br>Apple Tree Partners has a further option to acquire one third of these options for US\$1,500,000.                        |
|   |  | <b>5,259,276</b><br>(Assuming the Upper Target Subscription)  |                     |                       |  |
| <b>Incentive Options</b>  | <b>Tranche 1</b>   |   | \$0.60              | Five years from Issue | The terms of these Options are summarised in <b>Section 12.5</b> .<br><br>All options will be issued but will not vest until the first anniversary of the Issue Date, provided the holder is still a director of the Company at that time <sup>1</sup> .   |
|   | R Thomas   | 200,000   |                     |                       |  |
|   | Dr Bennett   | 100,000   |                     |                       |  |
|   | Dr Wade  | 100,000   |                     |                       |  |
|   | Inteq Limited  | 200,000   |                     |                       |  |
|   | <b>Tranche 2</b>   |   |                     |                       |  |
|   | R Thomas   | 200,000   | \$1.00              | Five years from Issue | All options will be issued but will not vest until the second anniversary of the Issue Date <sup>1</sup> .   |
|   | Dr Bennett   | 100,000   |                     |                       |  |
|   | Dr Wade  | 100,000   |                     |                       |  |
|   | Inteq Limited  | 200,000   |                     |                       |  |
|   | <b>Tranche 3</b>   |   |                     |                       |  |
|   | R Thomas   | 100,000   | \$1.50              | Five years from Issue | All options will be issued but will not vest until the third anniversary of the Issue Date <sup>1</sup> .  |
|   | Dr Bennett   | 50,000  |                     |                       |  |
|   | Dr Wade  | 50,000  |                     |                       |  |
|   | Inteq Limited  | 100,000   |                     |                       |  |
|   |  | <b>Total: 1,500,000</b>                                       |                     |                       |  |
|   |  |   |                     |                       | <sup>1</sup> Inteq Limited's options are vested  |
| <b>Total Options 17,803,761</b><br>(At the Upper Target Subscription) |  |   |                     |                       |  |

The total pro-forma number of Shares and Options to acquire Shares on issue by the Company will be 175,805,761 assuming the Upper Target Subscription under the Offer and the US Private Placement and the Company issues up to 11,044,685 options under the Employee Share Option Scheme. The Company has also agreed to issue convertible notes in the amount of \$1,420,000 to Apple Tree Partners on the terms summarised in **Section 12.5**.



### 9.5 Contingent liabilities

There are no contingent liabilities for the Company, other than as already disclosed.

### 9.6 Taxation matters

HeartWare is an Australian incorporated company with its central management and control in Australia, which will be listed on the ASX, and therefore, the Company will be regarded as a tax resident of Australia and subject to Australian taxation rules. In the future, the Australian tax entities will provide management services and carry out other business activities of HeartWare which may include clinical trials, continued product development, marketing and ultimately sales activity. However, the current business operations, research and development and ownership of intellectual property will be conducted by its wholly owned subsidiary, HeartWare, Inc., which is domiciled in the United States. The tax implications for Australian investors in HeartWare are set out below.

#### *Taxation of HeartWare*

Australian corporate income tax of 30% of taxable income shall apply to the Australian source profits of HeartWare. The tax paid will give rise to franking credits from which the company shall be able to pay franked dividends. To the extent the U.S. subsidiary, HeartWare, Inc., pays a dividend to the Company, this income will be 'non-exempt non-assessable' income. Such income will be credited to a foreign dividend account ("FDA") from which dividends can be paid to non-residents free of Australian withholding tax. No credit for United States ("U.S.") corporate tax or U.S. withholding tax, if any, is available to HeartWare as the dividend income is not assessable to the company in Australia.

Due to the recent U.S. enacted tax legislation, Section 7874 of the United States Internal Revenue Code ("**Section 7874**"), HeartWare's overall effective corporate tax rate may be higher than the Australian nominal rate of 30%. Under Section 7874, HeartWare expects to be taxed by the United States Internal Revenue Service ("**IRS**") as if it were a U.S. Corporation. As a result, income from the non-U.S. operations of HeartWare Limited and its subsidiaries may be subject to U.S. taxation even though such income generally would not have been subject to U.S. taxation if the Company were treated as an Australian Corporation. Accordingly, the enactment of Section 7874 may result in a net increase in the Company's tax burden.

Although HeartWare does not anticipate paying any cash dividends in the immediate future, any dividends distributed by HeartWare to Australian shareholders who are not U.S. citizens (or residents) may be subject to U.S. withholding tax at rates of up to 15%. If the Australian shareholder were an Australian tax resident owning more than a 10% interest in the Company, the rate of withholding may be limited to 5%. Australian shareholders may not receive credit for the payment of such withholding tax, as the Company is recognised by the Australian tax authorities as an Australian tax resident entity and a U.S. domiciled entity by the IRS.

Due to Section 7874 being enacted recently, the potential application of the new law to the Company and its shareholders is subject to some uncertainty and any potential investor is encouraged to consult with their own tax advisor.

#### *Dividends paid by HeartWare, Inc.*

Under the recently re-negotiated Australia-U.S. Double Taxation Arrangement ("**DTA**"), any dividends paid to HeartWare by HeartWare, Inc., 12 months after the acquisition of HeartWare, Inc., shall not be subject to U.S. withholding tax. Section 7874 also results in no withholding tax, as the IRS would view both entities as a U.S. corporation subject to only a single level of U.S. taxation.

### *Dividends paid by HeartWare*

#### *Residents of Australia*

In respect of unfranked dividends paid to Australia tax residents, the dividend will be assessable in full with no franking credits or foreign tax credits attached. To the extent that Australian tax has been paid on the Australian source profits, the dividend will be capable of being franked and the franking credit available to offset against Australian tax payable on the grossed up Australian dividend. We also note the potential for U.S. withholding tax arising under Section 7874 in respect of dividends paid to Australian resident shareholders by HeartWare as set out above.

#### *Non-residents of Australia*

In respect of unfranked dividends paid to non-residents of Australia, the rate of withholding tax, prima facie, shall be:

- U.S. residents and residents of countries with which Australia has a double tax agreement – 15%
- U.S. residents (also United Kingdom residents) that is a company which holds directly at least 10% of the voting power in the company paying the dividend – 5%
- Tax residents of a country that does not have a DTA with Australia – 30%

Potential investors should consult their own tax advisors regarding the tax consequences of an investment in the Company. Such tax consequences are potentially complex and will not be the same for all persons. Among other potential issues, shareholders may be subject to taxation on any gain recognised upon their sale or other disposition of any Shares of the Company acquired.

Where the unfranked dividend paid to a non-resident consists of a foreign dividend account declaration amount' (paid from the FDA) – the dividend is exempt from Australian withholding tax in accordance with Section 128B (3) (gaa) Income Tax Assessment Act 1997.

Given that significant revenue will be generated in the U.S. it is probable that dividends paid to non-residents shall be able to be paid out of the FDA, and accordingly, be free of Australian withholding tax.



# 10 Independent Accountant's Report

Grant Thornton 

HeartWare Limited; and  
HeartWare, Inc.  
3351 Executive Way  
Miramar, Florida  
33025-3935  
UNITED STATES OF AMERICA

15 December 2004

## INDEPENDENT ACCOUNTANT'S REPORT

Dear Directors

### HEARTWARE LIMITED

We have prepared this Independent Accountant's Report on the pro-forma Balance Sheet as at 30 September 2004 of HeartWare Limited ("**HeartWare**" or the "**Company**", which is a newly incorporated entity) and its controlled entity, the acquisition of HeartWare, Inc. (collectively the "**Consolidated Entity**"), relating to the initial public offering of approximately 60 to 70 million new fully paid ordinary Shares at an offer price of \$0.50 per share to raise approximately, but not more than, the Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date (the "**Offer**"). The Offer assumes completion of the acquisition of all the Series B and Common Stock of HeartWare, Inc. as at that date, together with the associated capital raising and the other pro-forma transactions set out in this report. The report is for inclusion in a prospectus dated on 17 December 2004 (the "**Prospectus**").

Expressions defined in the Prospectus have the same meaning in this report.

### Background

HeartWare is an Australian domiciled holding company. HeartWare is proposing an initial public offering on the Australian Stock Exchange Limited ("**ASX**") by acquiring 100% of the Common Stock and the Series B Stock in HeartWare, Inc. an unlisted company, incorporated in the State of Delaware, United States (the "**Acquisition**").

The purchase consideration for the Acquisition is \$44.0 million, payable in Shares in the Company at \$0.50 per Share, immediately after the Offer is closed.

HeartWare, Inc. also has existing Series A-1 and Series A-2 stock on issue, which will remain after the Acquisition. This stock has no rights other than a potential liquidation distribution if HeartWare, Inc. is ever liquidated.

The Company is offering investors, under this Prospectus ("**Offer**") and in a separate US private placement discussed further in **Section 12.12** of this Prospectus ("**US Private Placement**"), to subscribe for Shares to raise approximately, but not more than, an aggregate Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date.

At an exchange rate of A\$1.00 = US\$0.8317 this equates to 60 million Shares at a price of \$0.50 per Share to raise \$30 million ("**Lower Target Subscription**") and at an exchange rate of A\$1.00 = US\$0.7129 this equates to 70 million Shares at a price of \$0.50 per Share to raise \$35 million ("**Upper Target Subscription**").

The Company reserves the right to allot less than 60 million Shares or more than 70 million Shares in order to raise not more than the Australian dollar equivalent of US\$24,950,000, calculated as at the allotment date.

All Shares being offered under this Prospectus and the US Private Placement will on issue rank equally in all respects with existing issued Shares.

The Offer is likely to be characterised as a proposal to establish a “new business” for the purpose of the Australian Foreign Acquisitions and Takeovers Act 1975 (Cth) (“FATA”). As a result, the Offer is subject to Foreign Investment Review Board (“FIRB”) approval unless such approval is no longer required by reason of a change in the law. The scheduled entry into force of the Australia-United States Free Trade Agreement on 1 January 2005, with the consequent amendment of FATA on that date, will increase the threshold for US investment to \$800 million in non-sensitive industries so that no FIRB approval of the Offer would be required.

The major shareholder of HeartWare, Inc. is Apple Tree Partners, a limited partnership formed in the State of Delaware, United States.

## Historical Financial Information

The historical financial information included in Section 9 of the Prospectus comprises the financial information for each of the following:

- HeartWare Limited (the “Company”);

*(A newly incorporated (and non-operating) entity incorporated on 26 November 2004 with 2,000 Shares in HeartWare Limited at \$0.50 per Share)*

- HeartWare Inc; and

*(Any reference to the accounts of HeartWare, Inc. for the year ended 31 December 2003 is a reference to the accounts of HeartWare, Inc., which were audited by Grant Thornton LLP in accordance with auditing standards generally accepted in the United States of America who issued an unqualified audit opinion with an explanatory paragraph relating to the Company's ability to continue as a going concern. Any reference to the unaudited accounts of HeartWare, Inc. for the 9 months ended 30 September 2004 is a reference to the accounts of HeartWare, Inc. which were reviewed by Grant Thornton LLP in accordance with Statements and Standards for Accounting and Review services issued by the American Institute of Certified Public Accountants.*

*These accounts have been subject to certain pro-forma adjustments set out in Section 9.3.1. The pro-forma adjustments include the restatement of these accounts in accordance with AEIFRS and the translation of these accounts into Australian dollars.)*

- The Consolidated Entity consisting of the above companies in accordance with the contemplated transactions set out in Section 9.3.1 of the Prospectus (the “Pro-forma Transactions”).

The historical financial information of each of the companies set out above (collectively referred to as “Historical Financial Information”) comprise the pro-forma adjusted historical Balance Sheet of the Consolidated Entity as at 30 September 2004, which assumes completion of the Pro-forma Transactions disclosed in Section 9.3.1 of the Prospectus.

## Scope

You have requested Grant Thornton Corporate (NSW) Pty Limited (“Grant Thornton Corporate Finance”) to prepare a report covering the pro-forma Balance Sheet as at 30 September 2004, which assumes completion of the Pro-forma transactions disclosed in Section 9.3.1 of the Prospectus.

In accordance with the terms of our engagement, this report does not address the future prospects or forecasts of the Company, nor risks associated with an investment in the Company.

## Review of Pro-forma Historical Financial Information

The historical Balance Sheet set out in **Section 9** of the Prospectus has been compiled from the accounts of HeartWare and the audited accounts of HeartWare, Inc. for the year ended 31 December 2003 and the accounts for the 9 months ended 30 September 2004 as described in **Section 9.3**. The Directors are responsible for the preparation of the historical Balance Sheet, including determination of the adjustments.

We have conducted our review of the historical Balance Sheet in accordance with the Australian Auditing and Assurance Standard AUS 902 "*Review of Financial Reports*". We made such inquiries and performed such procedures as we, in our professional judgement, considered reasonable in the circumstances including:

- analytical procedures on the newly incorporated pro-forma Balance Sheet of the Company as at 30 September 2004;
- analytical procedures on the reviewed pro-forma Balance Sheet of HeartWare, Inc. as at 30 September 2004;
- a review of work papers, accounting records and other documents;
- a review of the assumptions used to compile the pro-forma Balance Sheet as at 30 September 2004;
- a review of the adjustments made to the pro-forma historical Balance Sheet as at 30 September 2004;
- a comparison of consistency in application of the recognition and measurement principles in Accounting Standards and other mandatory professional reporting requirements in Australia, and the accounting policies adopted by the Company disclosed in **Section 9** of the Prospectus; and
- enquiry of Directors, management and others.

These procedures do not provide all the evidence that would be required in an audit, thus the level of assurance provided is less than given in an audit. We have not performed an audit and, accordingly, we do not express an audit opinion.

## Conclusion

Based on our review, which is not an audit, nothing has come to our attention, which causes us to believe that:

- the pro-forma Balance Sheet has not been properly prepared on the basis of the Pro-forma Transactions; and
- the pro-forma historical Balance Sheet, as set out in **Section 9.3** of the Prospectus does not present fairly the pro-forma historical Balance Sheet of the Company as at 30 September 2004 in accordance with the recognition and measurement principles prescribed in Australian Accounting Standards, Australian Equivalent International Reporting Standards and other mandatory professional reporting requirements, and accounting policies adopted by the Company disclosed in **Section 9.3.3** of the Prospectus.

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### **Subsequent events**

Apart from the matters dealt with in this report, and having regard to the scope of our report, to the best of our knowledge and belief, no material transactions or events outside of the ordinary business of the Company have come to our attention that would require comment on, or adjustment to, the information referred to in our report or that would cause such information to be misleading or deceptive.

### **Independence or disclosure of interest**

Grant Thornton Corporate Finance does not have any interest in the outcome of this Offer other than normal professional fees that will be received.

Grant Thornton NSW is the auditor of the Company.

Yours faithfully

**GRANT THORNTON CORPORATE (NSW) PTY LTD**



S T Griffin  
Director



## 11 Risk Factors

To appreciate the risks associated with an investment in the Company, this Prospectus should be read in its entirety. Potential investors should be aware that an investment in the Company involves various risks and should be regarded as speculative given the current stage of development of the Company. Investors should also note that risks are associated with any investment in the stock market.

The Company's business activities are subject to risk factors both specific to its business activities and those of a general nature. If any of the risks associated with the Company occur, the Company's business, results of operations, financial condition and prospects could be materially and adversely affected, which could result in the loss of all or part of your investment. Some of these factors can be mitigated by appropriate commercial action, although many are outside the control of the Company and cannot be mitigated.

Potential investors should carefully consider these risk factors, together with the other information in this Prospectus, seek their own professional advice in relation to the risks associated with an investment in the Company and should make their own assessment as to whether to invest in the Company.

The principal risk factors applicable to the Company include, and are not limited to, the following:

### 11.1 General Risks

#### *General economic conditions*

Changes in the general domestic and international climate may adversely affect the financial performance of the Company and its products. Factors that may contribute to a change in the general economic climate include industrial disputes, inflation, political and social reform.

#### *Inflation and currency fluctuations*

Substantially all the Company's revenues, expenses and liabilities are denominated in US dollars. The Company believes that in the future it will generate substantially all of its revenues in US dollars, Euros and other non-Australian currencies and will incur some of its expenses, principally related to Australian clinical trials and regional product development, in Australian dollars.

As a result, the Company's financial results will be subject to the effects of exchange rate fluctuations with respect to foreign currency.

### 11.2 Risks Related to the Company's Business

#### *Pre-clinical trials*

To date, HeartWare has performed a series of pre clinical trials of its HVAD in vitro and in animals. The design development animal trials for the HVAD were conducted to assess anatomical fitting, design, pump mechanics and long term compatibility with blood components and were completed in 2001. Currently, pre good laboratory practices ("GLP") animal trials are being conducted with GLP animal trials for the HVAD planned for early 2005.

There is no guarantee that the HVAD will work in the pre GLP animal trials, GLP animal trials or in the human clinical trials. There is a risk of unforeseen issues arising from the pre GLP animal trials, GLP animal trials or the human clinical trials. These issues may require rectification or design changes to the HVAD. There is no guarantee that these issues will be able to be addressed at all.

Any rectification work or design change would adversely impact the timing of the Company's milestones and the cost of the Company's commercialisation.

### *Regulatory approvals*

There is no guarantee that the Company's LVAD will obtain regulatory approvals for clinical testing or subsequently, marketing and distribution. Even if such approvals are granted, there is no guarantee as to the time taken or cost involved. Before the Company can commence its clinical trials it requires approvals from:

- the relevant Investigational Review Boards in each of the Company's chosen clinical trial centres; and
- the relevant regulatory bodies (TGA in Australia, Competent Authorities in the EU and the FDA in the United States).

There is no guarantee that these approvals will be obtained, or that there will not be a delay, each of which will impact the Company's ability to complete its regulatory process in order to sell its products.

In the United States, prior to conducting human clinical trials, the Company will need to obtain approval of an Investigational Device Exemption application from the FDA. Before the Company can sell its products in the United States, "clearance to market" is required from the FDA, which is a lengthy and uncertain process. The procedure for submitting an application for Pre Market Approval ("PMA") is lengthy, expensive and typically requires extensive pre-clinical and clinical trial data as well as considerable technical data. Submitted data will need to be obtained in accordance with FDA Quality Systems Regulations.

The Company is planning to use the clinical trial data obtained in Australia and the European Union in order to facilitate a more expedient US approval process. There is a risk that the FDA may not allow those results to be used in the PMA application which would result in a delay and increase in costs of US approvals.

The Company may not obtain approval of PMA applications with respect to some or all of its products. If the Company fails to obtain timely clearance or approval for its products, it will not be able to market and sell its products in the US, affecting the ability to generate revenue. The FDA may also limit the claims that can be made about the product which could reduce its market attraction.

The Company must also adhere to the FDA's Quality Systems Regulations, which include production design controls, testing, quality control, storage and documentation procedures. If the Company does not comply, the FDA may withdraw clearance to market, require a product recall or take other enforcement action.

Sales of the Company's products in other jurisdictions are subject to regulatory requirements that vary from country to country. The time and cost required to obtain approvals from these countries may be longer or shorter than that required for FDA approval, and requirements for licensing may differ from those of the FDA.

Federal, state and local market laws and regulations regarding the manufacture and sale of the Company's products are subject to future changes, as are administrative interpretations and policies of regulatory agencies. If the Company fails to comply with applicable federal, state or local market laws or regulations, it could be subject to enforcement actions. Enforcement actions could include product seizures, recalls, withdrawal of clearances or approvals, and civil and criminal penalties, which in each case would harm the Company's business.





## 11 Risk Factors

### *Core technology*

The Company's future revenues are highly dependent upon the commercialisation of products based on its technology. To commercialise its technology the Company intends to form alliances with key distributors, partners and manufacturers. The Company's future revenues rely on the achievement of these goals and the required regulatory approvals. However, no assurance can be given that the Company will succeed in the commercialisation of its technology.

The markets in which the Company operates are characterised by the continual search for technological advances that deliver improved performance, reliability, patient quality of life and reduced cost. The Company's growth and future financial performance will depend on its ability to enhance its existing technology and develop and introduce new products on a timely basis to keep pace with competitive technological developments and evolving industry requirements. If the Company is unable to achieve the above, this may have a material adverse effect on its business.

The research and development required for technology enhancements and new products is complex and uncertain, and requires significant investment and high levels of innovation. If the Company fails to anticipate or respond adequately to technological developments or customer needs, or if the Company experiences any significant delays in product development or introduction, the Company's products may become obsolete and the Company may not be able to sustain or grow its business. Furthermore, there is no assurance that new products introduced by the Company will gain widespread market acceptance.

### *Hospitals not conducting destination therapy*

If hospitals do not conduct Destination Therapy procedures using the Company's circulatory assist devices, the Company's revenues will be diminished. The number of Destination Therapy procedures actually performed is dependent on many factors, most of which are out of the Company's direct control, including:

- The number of Medicare (Australia) and CMS (United States) sites approved for Destination Therapy.
- The clinical outcomes of Destination Therapy procedures.
- Cardiology and referring physician education, and their commitment to Destination Therapy.
- The economics of the Destination Therapy procedure for individual hospitals, which includes the costs of the VAD and related pre and post operative procedures and their reimbursement.
- The economics of not conducting a Destination Therapy procedure, including the costs and related reimbursements of long-term hospitalisation.

The different outcomes of these and other factors, and their timing, may have a significant negative impact on the Company's future results.

### *Manufacturing*

The Company will depend on a number of suppliers in successfully manufacturing clinical and commercial quantities of its products. If any critical suppliers do not deliver for any reason, contractual or otherwise, the business may be seriously harmed financially. Additionally, the Company itself may experience problems or delays in its manufacturing process, which again may harm the financial status or reputation of the Company.

The Company's business plan is predicated on entering into agreements with one or more external parties to manufacture components of the Company's technology. If the Company is unable to secure agreements with these manufacturers on favourable terms or at all, then its ability to commercialise its technology and expand its operations will change from that currently envisaged.

### *Product liability*

Product liability claims could damage the Company's reputation and financial results.

The Company's business will be exposed to an inherent risk of potential product liability claims related to the trials, manufacturing, marketing and sale of human medical devices. Once the Company commences clinical trials it anticipates obtaining a limited amount of clinical trial and product liability insurance. Insurance may not be able to be maintained or increased on acceptable terms, and such insurance may not provide adequate coverage against potential liabilities. A successful claim brought against the Company in excess of, or outside of, its insurance coverage could seriously harm the Company's financial condition and operations. Claims, regardless of their merit or potential outcome, may also reduce the Company's ability to obtain doctor endorsement of its products or expand the business.

The Company will implement extensive testing programs to identify material defects to its technology that could pose a risk.

### *Intellectual property*

The Company relies on a combination of patents, trade secrets and copyright, together with non-disclosure and confidentiality agreements, to establish and protect its proprietary rights in its technologies. If the Company is unable to adequately protect its intellectual property rights or becomes subject to a claim of infringement, its business may be materially adversely affected.

The Company currently has patents that have been granted or under application. The Company cannot be certain that patents will be issued with respect to any of the Company's pending or future patent applications. In addition, the Company does not know whether any issued patents will be upheld as valid or proven enforceable against alleged infringers or that they will prevent the development of competitive patents. At some stage a competitor may allege that the Company infringes patents of the competitor which may lead to either litigation or cross licensing or both.

In recent years, there has been significant litigation involving medical device patents and other intellectual property rights. From time to time, third parties may assert patent, copyright, trademark and other intellectual property rights to technologies used in the Company's business.

Any claims, with or without merit, could be time-consuming, result in costly litigation, and divert the efforts of the Company's technical and management personnel. If the Company is unsuccessful in defending itself against these types of claims, the Company may be required to do one or more of the following:

- stop selling its products that use or incorporate the challenged intellectual property;
- attempt to obtain a license to sell or use the relevant technology or substitute technology, which license may not be available on reasonable terms or at all; or
- redesign those products that use the relevant technology.

In the event a claim against the Company was successful and the Company could not obtain a license to the relevant technology on acceptable terms or license a substitute technology or redesign the Company's products to avoid infringement, the Company would be significantly harmed.

The Company believes that it has implemented an internal intellectual property management system and strategy to promote effective identification and protection of its inventions and know-how but no assurance can be given that such a system will be entirely effective.

### *Ventracor patent demand*

On 13 December 2004 HeartWare, Inc. received a letter from one of its competitors, Ventracor Limited. The letter demands that HeartWare, Inc. “cease and desist from all infringing commercial activities involving the HVAD devices in issue and to account to our client [Ventracor Limited] for any past [unspecified] damages”. In the letter a response was sought by Friday 17 December, 2004. Subsequently on 14 December, 2004, Ventracor stated to the Company that Ventracor would be prepared to withdraw its letter if the Company enters into negotiations in regard to a potential cross-licence of patents prior to Christmas, 2004.

Based on the above and other correspondence and discussions with Ventracor and in particular having regard to the timing of the letter, the Offer and the US Private Placement, the Board of the Company believes that the Ventracor letter is opportunistic and designed to disrupt the Company’s capital raising efforts. Moreover, the Board believes that the demand has no validity whatsoever and is frivolous in nature. The Board has responded formally to Ventracor denying any infringement on the part of HeartWare, Inc. and informing Ventracor that any litigation or other action that may be commenced by it in relation to the specified patents or any other patents will be vigorously defended by HeartWare, Inc., including the seeking of appropriate damages.

### *Doctors may not use or continue to use HeartWare’s products*

Physicians may not accept or continue to accept the Company’s products and products under development.

The success of the Company’s current and future products will require acceptance or continued acceptance by cardiovascular surgeons, cardiologists and other medical professionals. Such acceptance will depend on clinical results and the conclusion by these professionals that the Company’s products are safe, cost-effective and acceptable methods of treatment. Even if the safety and efficiency of the Company’s future products are established, physicians may elect not to use them for a number of reasons. These reasons could include the cost of the Company’s circulatory assist devices and unfavourable reimbursement from health care payers. Also, economic, psychological, ethical and other concerns may limit general acceptance of the Company’s circulatory assist devices.

The ability of the Company to conduct human clinical trials will also be dependent upon cardiovascular surgeons, cardiologists and other medical professionals, recommending their patients participate in human clinical trials. Where the trials are required to be conducted on a randomised basis against an approved device, such as in the US, the ability of the Company to conduct its trials may be limited by the characteristics and performance of the approved device and the desire of cardiovascular surgeons, cardiologists and other medical professionals to recommend patients for a randomised human clinical trial.

### *Third party reimbursement*

Part of the Company’s success is contingent upon third party reimbursement from either government providers such as Medicare or other insurance providers. Any limitation on, or decrease in the ability for patients, surgeons or hospitals to be reimbursed could effect the Company’s ability to generate revenues.

Currently, the US Center for Medicare and Medicaid Services has approved reimbursement for implanted circulatory assist devices for an average of US\$136,000. The Company believes that its products will be eligible for Medicare reimbursement in the US and therefore other insurance reimbursement during US clinical trials. Some payors do not reimburse the cost of investigational devices, and therefore may not reimburse the cost of HeartWare’s devices prior to commercialisation.



# 11 Risk Factors

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## *Market and competition*

The Company faces competition from other circulatory assist device and heart assist companies which may have greater research and development, management, financial, technical, manufacturing, marketing, sales, and other resources than those currently available to the Company. There can be no assurance that the Company will be able to compete successfully against its current and future competitors.

There are an increasing number of alternative treatments and circulatory assist device competitors in the area of congestive heart failure. The Company may successfully commercialise its product and obtain regulatory approval but may fail to successfully compete against these competitors or alternative treatments.

## *Sales channels*

HeartWare will rely on a number of distributors and partners in selling its product. If these distributors or partners fail to assist in distributing the product, revenues and growth will be limited.

## *International markets*

The Company is intending to sell into the Australasian, Asian, European and American markets. The Company's ability to sell product into these markets may be constrained by culture, relationships, ethics, regulatory approvals, financial incentives and other factors.

## *Growth in the business*

The Company is projecting considerable future growth in its business. To achieve this growth in an efficient and timely manner, the Company will have to maintain close co-ordination among its technical, accounting, sales and marketing and research and development departments and maintain adequate control systems. If the Company cannot manage successfully its anticipated future growth, its costs may increase, its growth could be impaired and it may not accurately anticipate and fulfil market demand for its technology. This could result in a loss of customers, revenues and earnings.

## *Reliance on key personnel*

The Company's success depends to a large degree on the continued services of its senior management and key personnel. The loss of their services, particularly to a competitor, could disrupt the Company's operations and harm its business.

## *Lack of capital*

The Company must raise capital to continue to commercialise its technology. If the Company is unable to raise sufficient capital on favourable terms, or at all, then its ability to operate in the future will be hindered.

The Company believes that the net proceeds from the Offer, together with available funds, should be sufficient to meet the Company's operating liquidity needs for at least 18 months. However, no assurance can be given that the Company will not require additional funds in the future to support the development of its business and technology, nor can it be guaranteed that such funds will be available if and when they are required.

## *Currency risk*

Changes in foreign currency exchange rates can affect the value of HeartWare's assets, liabilities, costs and revenues. This is particularly true of HeartWare's activities in the United States where



## 11 Risk Factors

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expenditures are incurred in US dollars. HeartWare may try to mitigate its exposure to exchange rate risks by using hedging transactions or holding funds in US dollars. HeartWare may suffer losses as a result of exchange rate fluctuations.

### *Quality issues*

FDA regulations require the Company to track materials used in the manufacture of its products, so that any problems identified in a finished product can easily be traced back to other finished product containing the defective materials.

The Company is implementing a Quality System. However, identified quality issues may require scrapping or expensive rework of the affected lot(s), not just the tested defective product and could also require shipments to be stopped.

In addition, since the Company's products are used in situations where a malfunction can be life threatening, identified quality issues can result in the recall and replacement, generally free of charge, of substantial amounts of product in the field. Any quality issue identified can therefore result in substantial costs and write-offs, which could materially impact the Company's financial results.

### *Legislation*

If the Company's technology or products based on its technology do not comply with applicable laws or if the Company is exposed to liability claims its business and financial results could be seriously harmed. Any imposition of liability that is not covered by the Company's insurance or is in excess of the Company's insurance coverage could have a material adverse effect on the Company's business, results of operations and financial condition.

Furthermore, changes in legislation and government policy could also negatively impact on the Company. The Company is currently unaware of any introduced or proposed bills, or policy, that may cause any specific changes to the Company's operations. No assurance can be given that the Company will be able to obtain any necessary licence required in the future or that future changes in laws or government policies affecting the Company's technology or products will not impose additional regulatory requirements on the Company, intensify competition in the industry or otherwise have a material adverse effect on the Company's business, financial condition and results of operations.

### *Catastrophic disasters*

The occurrence of a catastrophic disaster or other similar events could cause damage to the Company's facilities and equipment, which would require cessation or curtailing of operations. The Company may be vulnerable to damage from various types of disasters, including earthquake, fire, terrorist acts, flood, hurricanes / tornadoes, power loss, communications failures and similar events.

If any disaster were to occur, the Company may not be able to operate at its facilities, which could seriously harm the business and operations, in particular because the premises require FDA approval, which could result in significant delays before the Company can manufacture product from a replacement facility. The insurance maintained may not be adequate to cover the losses resulting from disasters or other business interruptions.

### *Third party reimbursement and cost containment*

HeartWare's products will be purchased primarily by hospitals, which then bill various third party payors for the services provided to the patients.



## 11 Risk Factors

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These payors, including Government entities, buying groups, private health insurance companies and managed care organisations, typically reimburse part or all of the reasonable costs and fees associated with these devices and the procedures performed with these devices. The reimbursement policies and practices of third party payors are subject to changes that might be unfavourable to HeartWare and such unfavourable changes could seriously harm sales. Some payors do not reimburse the cost of investigational devices, and therefore may not reimburse the cost of HeartWare's devices prior to commercialisation.

### *US Securities laws*

HeartWare is currently considered a US domestic issuer for the purposes of the US securities laws. As such, changes in US securities laws and the requirements on the Company to comply with those laws may have an adverse effect on investors.

The Offer is proceeding on the basis that neither the Offer nor the Shares are required to be registered with the SEC under the US Securities Act. Changes in the legislation may, at a future time, require the Shares to be registered under the US Securities Act. In like manner, the reporting requirements of the Company may change with the Company being required to meet more onerous requirements. In this case, the costs of compliance with both US and Australian laws and legal regulations may increase significantly.

### *US tax laws*

US tax laws may change including provisions relating to rates of tax and withholding tax on dividends payable to persons not resident in the United States.

## 11.3 Risks Related to the Offer

### *Share investment*

Applicants should be aware that there are risks associated with share investment. It is important to recognise that:

- share prices and dividends may fall as well as rise
- the price at which the Company's Shares trade may be above or below the Issue Price of those Shares; and
- concentrated shareholdings may affect liquidity of the Shares.

### *Not proposing to pay dividends*

The Company is at a development stage with no pre-tax profit. Any profitability in the future will be dependent on the successful research, development, manufacture, sales and marketing of the Company's products. The Shares issued under this Prospectus carry no guarantee with respect to the profitability, the payment of dividends, return of capital or the price at which the Shares may trade on the ASX.

The Company does not anticipate paying any cash dividends on its ordinary Shares in the foreseeable future and intends to retain all future earnings to fund the development of its business.

### *Use of funds*

The Company's management will have broad discretion in spending the net proceeds of the Offer and the US Private Placement and the Company cannot assure investors that it will use the net proceeds in a way that will ultimately lead to profitability.



## 12 Additional Information

The key provisions of each material agreement and certain other documents are summarised below. The summary of each document is not intended to be exhaustive.

### 12.1 Incorporation of HeartWare Limited

The Company was incorporated on 26 November 2004 in the State of Victoria, Australia.

### 12.2 Incorporation of HeartWare, Inc.

HeartWare, Inc. was incorporated on 8 April 2003 in the state of Delaware, United States of America.

HeartWare, Inc. has authorised capital consisting of Series A-1 Non-Voting Preferred Stock ("**Series A-1 Stock**"), Series A-2 Non-Voting Preferred Stock ("**Series A-2 Stock**"), Series B Convertible Participating Preferred Stock ("**Series B Stock**") and Common Stock ("**Common Stock**"). Series A-1 Stock has a US\$10 per share junior liquidation preference and is not convertible. Series A-2 Stock has a US\$21 per share junior liquidation preference and is not convertible. Series B Stock has a US\$10 per share senior liquidation preference and is convertible. The number of Shares of Common Stock which results from a Series B Stock conversion is calculated by (i) multiplying the aggregate number of outstanding Shares of Series B Stock to be converted by (ii) the quotient obtained by dividing the Series B Conversion Value (currently US\$10.00) by the Series B Conversion Price (currently US\$10.00) then in effect at the time of conversion. HeartWare currently has outstanding:

- 626,652 Shares of Series A-1 Stock; 18,000 owned by Apple Tree Partners and 608,652 owned by certain former holders of Shares of preferred stock of Kriton Medical, Inc., the predecessor of the HeartWare, Inc. business.
- 436,443 Shares of Series A-2 Stock; 1,200 owned by Apple Tree Partners and 435,243 owned by certain former holders of Shares of preferred stock of Kriton Medical, Inc.
- 603,130 Shares of Series B Stock; 582,610 owned by Apple Tree Partners and 20,520 owned by the Kriton Medical Angel Investors.
- 0 Shares of Common Stock.

Apple Tree Partners is the majority owner of HeartWare, Inc. with 98.87% ownership of the voting stock on a converted basis. The Kriton Medical Angel Investors are the minority owners of HeartWare, Inc. with an aggregate 1.13% ownership voting stock on a converted basis. However, the Kriton Medical Angel Investors have each executed a Voting Agreement, dated as of July 10, 2003, in which they have agreed to vote their Shares as instructed by Apple Tree Partners.

The holders of Series B Stock constituting a majority of the voting power of the outstanding Shares of Series B Stock, voting separately as a separate class, are entitled to elect up to three Directors of HeartWare, Inc. HeartWare, Inc. currently has one Director, Dr Seth Harrison, on its Board of Directors. HeartWare, Inc. operates under standard by-laws. HeartWare, Inc. is qualified to do business as a foreign corporation in the State of Florida.

### 12.3 HeartWare, Inc's acquisition of substantially all the assets of Kriton Medical

The business currently conducted by HeartWare, Inc. was previously owned and conducted by Kriton Medical, Inc. ("**Kriton Medical**"). In May 2003, Kriton Medical filed for protection from creditors under Chapter 11 of the US Bankruptcy Code. On 20 May 2003, Kriton Medical and Apple Tree Partners proposed a Joint Plan of Liquidation for Kriton Medical ("**Plan of Liquidation**"). On 20 June 2003, the United States Bankruptcy Court of the Southern District of Florida issued a court order confirming the Plan of Liquidation ("**Court Order**"). The Court Order together with a supplemental court order approving a settlement between Apple Tree Partners and the Kriton Medical Angel Investors, issued on 3 July 2003 ("**Settlement Order**"), approved the sale of substantially all the assets of Kriton Medical to HeartWare, Inc. ("**Asset Sale**"). The Asset Sale occurred on 10 July 2003. Pursuant to the Court Order and the Settlement Order, HeartWare, Inc. and Kriton Medical executed an Asset Purchase Agreement pursuant to which HeartWare, Inc. agreed to purchase substantially all of the assets of Kriton Medical and to assume certain secured indebtedness of Kriton Medical owed to Apple Tree Partners in the aggregate principal amount of up to US\$3,064,596 ("**Apple Tree Partners Indebtedness**"). With the exception of the Apple Tree Partners Indebtedness, by virtue of the Court Order, HeartWare, Inc. took the Kriton Medical assets free and clear of any and all liens, security interests, encumbrances and claims.

In connection with the Asset Sale, also on 10 July 2003, HeartWare, Inc., Apple Tree Partners and the Kriton Medical Angel Investors were ordered to enter into a Stockholder's Agreement. The Stockholder's Agreement places restrictions on the transfer of Securities owned by the Kriton Medical Angel Investors ("Kriton Medical Angel Investors Securities"), grants HeartWare, Inc. and Apple Tree Partners the right of first offer on any sale of Kriton Medical Angel Investors Securities, requires all stockholders (as defined therein), including the Kriton Medical Angel Investors, to vote for, and raise no objections against, and waive dissenters and appraisal rights (if any) with respect to, any sale of the business of HeartWare, Inc. approved by the stockholders holding at least 50% of the Common Stock on an as converted basis, and sell its Shares in any such sale, and in that regard to execute and deliver any documentation required in connection therewith.

On 10 July 2003, each of the Kriton Medical Angel Investors executed a Subscription for Shares and Voting Agreement in which the Kriton Medical Angel Investors agreed to vote the Shares of Series B Stock owned by the Kriton Medical Angel Investors as instructed by Apple Tree Partners in writing. The Kriton Medical Angel Investors further agreed not to transfer their Shares without Apple Tree Partners' consent and subject to the Stockholders Agreement, grant any proxy, participate in a voting trust or agreement, or otherwise restrict their Shares in any way.

### 12.4 Constitution

A summary of the principal rights attaching to all Shares and the key provisions of the Constitution is below.

#### Voting

Subject to the Constitution, at a general meeting:

- on a show of hands, each person present who is, or who is registered as, a member of the Company, has one vote; and
- on a poll each member has one vote for each Share held.

Two members present in person or by proxy constitute a quorum for a general meeting.





## 12 Additional Information

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### *General meetings and notices*

Each member is entitled to receive notice of, and to attend and vote at, general meetings of the Company.

### *Dividends*

Subject to any special rights and restrictions attaching to a Share, the Board may declare that dividends are payable to members on each Share in proportion to the amount for the time being paid up on that Share.

### *Power to issue Shares*

Subject to the Corporations Act, the Constitution and the ASX Listing Rules, the Board may allot and issue Shares to any person on such terms and with such rights as the Board determines.

The Board may determine that Shares are to be issued with preferred, deferred or other special rights or restrictions, whether in regard to dividends, voting, return of share capital, payment of calls or otherwise.

### *Transfer of Shares*

There are restrictions on transfer that are set out in **Section 12.12** of this Prospectus having regard to the provisions of Regulation S under the US Securities Act. Subject to the Constitution and the provisions of Regulation S, the Shares will be freely transferable by sale on ASX:

- electronically by a proper transfer effected in accordance with the Corporations Act, ASX Listing Rules and ASTC Settlement Rules; or
- by an instrument in any usual or common form or in any other form that the Board approves.

If permitted by the ASX Listing Rules or the ASTC Settlement Rules, the Board may:

- request the ASTC to apply a holding lock to prevent a transfer of Shares through CHES; or
- decline to register any transfer of Shares.

### *Refusal to register*

The Board must decline to register any transfer of Shares if the ASX Listing Rules require the Company to do so; the transfer is in breach of the ASX Listing Rules or a Restriction Agreement; or the transfer is not made in accordance with the provisions of Regulation S of the US Securities Act, pursuant to registration under the US Securities Act, or pursuant to an available exemption from registration.

### *Proportional takeover bid*

If an offer is received for a specified proportion of the Shares of the Company, a resolution of Eligible Shareholders (a person, other than the bidder or an associate of the bidder, who, as at the end of the day on which the first offer under a bid was made, held Shares in the class of Shares to which the bid relates) must approve the takeover bid before it may take effect. If approval is obtained, the offer may proceed. If approval is not obtained, the offer will be taken to have been withdrawn.



## 12 Additional Information

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The rule does not apply to a takeover bid for all of the Shares of the Company. The rule ceases to apply at the end of three years following its date of adoption or last renewal.

### *Non-marketable parcels*

Subject to the Corporations Act, the ASX Listing Rules and the ASTC Settlement Rules, the Company may sell Shares of a member who holds less than a marketable parcel of Shares by giving that member written notice, not less than 42 days prior to the sale. The power may be invoked only once in any 12 month period.

### *Winding-up rights*

If the Company is wound up, any property that remains (after satisfaction of all debts and liabilities of the Company, the payment of the costs, charges and expenses of winding up and any adjustment of the rights of the contributories among members) must be distributed among the members equally.

### *Directors*

The Company must have at least three directors. At least two directors must ordinarily reside in Australia.

A resolution of the Board must be passed by a majority vote. The chair of the meeting has no casting vote in the event that there is an equality of votes.

### *Indemnity and insurance*

The Company may indemnify each officer, director and secretary out of the assets of the Company against any liability incurred or to be incurred by the officer, director or secretary in or arising out of the discharge of their duties.

The Company may pay the insurance premium for an officer, director or secretary in respect of a contract of insurance in relation to liability incurred by the officer, director or secretary arising out of the activities of the Company and their proper performance of any duty.

## 12.5 Options and convertible notes

### *Employee Share Option Plan*

The Company has adopted an Employee Share Option Plan which allows the Company or an associated body corporate to grant options over Shares and issue Shares to eligible employees and Directors of the Company. The Employee Share Option Plan is designed to provide eligible employees and Directors of the Company with the opportunity to participate in the growth and success of the Company and to provide an incentive for such participants to have a greater involvement with, and to focus on the long term goals of the Company. The Directors believe that this is important for the long-term development of the Company.

The Company has agreed to issue options under the Employee Share Option Plan to certain employees and Directors of the Company or an associated company. Some of these options issued to US based employees vest immediately on issue, with the balance vesting on certain anniversaries of the issue date.



## 12 Additional Information

An offer of options under the Employee Share Option Plan is not permitted if the total of:

- the number of Shares which would be issued if all outstanding options were exercised; and
- the number of Shares issued during the previous five years pursuant to the exercise of options under the Employee Share Option Plan or under any other employee share scheme adopted by the Company,

exceeds 10.0% of the total number of issued Shares at the time of the offer of options.

Each option issued under the Employee Share Option Plan allows the holder to subscribe for and be issued the number of Shares specified in the Option (which is at the discretion of the Board). The exercise price (or the formula for determining the exercise price) for each option is determined by the Board prior to the offer, but for options issued after the Company is listed, the exercise price must not be less than the weighted average sale price of Shares sold during the five days (or such other period as the Board determines) prior to the issue of the option.

Options may generally be exercised after they have vested and prior to the specified expiry date if applicable exercise conditions are met. Options issued after the Company is listed will vest as to 25% on each anniversary of the issue date. Exercise conditions are determined by the Board and may include performance criteria set by the Board. In addition, options may be exercised at any time, subject to approval by the Board of Directors, if the Company enters into a scheme of arrangement or a takeover occurs, or if an entity acquires a relevant interest in sufficient Shares to enable them to replace all or a majority of the Board of Directors.

There are a number of events that may cause options to lapse under the plan including, for example, where a participant ceases to be an employee or Director of the Company for whatever reason.

Option holders will not be entitled to participate in new issues of capital offered to shareholders of the Company. However, in the event of any bonus issue of Shares by the Company, the number of Shares which an option holder is entitled to on exercise of the option will be adjusted accordingly.

Options issued under the plan are not transferable, except during a takeover in which case the options can be transferred to the bidder.

A copy of the rules of the Employee Share Option Plan may be inspected at the registered office of the Company during normal business hours by appointment with the Company Secretary.

### *Incentive Options*

The Company has agreed to issue a total of 1,500,000 incentive options to subscribe for fully paid ordinary Shares in the Company on a one for one basis to the following:

| Name   | Number of Options |
|--|-------------------|
| Robert Thomas, Chairman                      | 500,000           |
| Dr Christine Bennett, Non-executive Director | 250,000           |
| Dr Denis Wade AM, Non-executive Director     | 250,000           |
| Inteq Limited                                | 500,000           |
| <b>TOTAL</b>                                 | <b>1,500,000</b>  |

The options are granted for no consideration and with the exception of the options issued to Inteq Limited, will vest in three tranches, 40% on the first anniversary of issue, 40% on the second anniversary of issue and 20% on the third anniversary of issue and all lapse on the fifth anniversary



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of issue. The Non-Executive Directors must be directors of the Company at the date they exercise tranches 2 and 3 of their options except in the case of Robert Thomas, where he has resigned as a director of the Company due to serious ill health which in the opinion of the board of the Company would prevent him from discharging his duties as a director of the Company. Inteq Limited's options are fully vested on issue.

The options will not be listed but the Company shall apply for listing of any Shares issued on exercise of the options.

The exercise price for each option exercised is \$0.60 for tranche 1, \$1.00 for tranche 2 and \$1.50 for tranche 3.

### *Shares to former Chief Executive Officer of Kriton Medical*

The Company has made a provision for the issue of up to 5,259,076 Shares to Dr Robert Fine, the former Chief Executive Officer of Kriton Medical, pursuant to three warrants issued by HeartWare, Inc. to Dr Fine under a Memorandum of Terms between Dr Fine and Apple Tree Partners which was entered into in connection with the Kriton Medical bankruptcy proceedings and the Asset Sale.

Under the terms of the three warrants issued by HeartWare, Inc. to Dr Fine, each will automatically, without any further action being taken by HeartWare, Inc. other than the delivery of the notice described below, become exercisable for Shares at an exercise price equal to the exercise price of options under the ESOP on the date of exercise of the warrants (expected to be \$0.20 per Share). Pursuant to the express terms of the warrants, HeartWare, Inc. intends to send a notice to Dr Fine, approximately 20 days prior to the Closing of the Offer, that the warrants will become exercisable for a period of 90 days from the Closing of the Offer.

The Company shall apply for listing of any Shares issued on exercise of the warrants.

The exercise price for each option is \$0.20 per Share. The options lapse 90 days after issue.

Apple Tree Partners and Dr Fine have entered into an Option Agreement under which Apple Tree Partners has an option to acquire the Shares issued to Dr Fine under one of the warrants for US\$500,000 and the Shares issued under another of the warrants for US\$1,500,000 (each option is in respect of one third of the total Shares covered by the three warrants issued to Dr Fine).

### *Option Terms*

The options issued to the Non-Executive Directors and Inteq Limited and deemed to be granted to Dr Fine include the following terms:

- a) The options do not confer rights to participate in new issues of securities of the Company, unless the option holder has first exercised the option and such exercise took place on or before the record date for determining entitlements to the issue;
- b) If there is a bonus issue of Shares by the Company, the number of Shares received on the exercise of any options, will include the number of bonus Shares that would have been issued if the options had been exercised prior to the record date for bonus issues. The exercise price will not change;
- c) In the event of any reorganisation (including consolidation, sub division, reduction or return) of the issued capital of the Company, the rights of the option holder including the number of options or the exercise price or both shall be reorganised (as appropriate) to the extent necessary to comply with the Listing Rules applying to a reorganisation of capital at the time of the reorganisation; and

- d) The options are not transferable, except to a partner, shareholder or officer, subsidiary, affiliate, affiliated partnership or other affiliated entity, family member, family trust or estate of a shareholder or officer of the option holder, without the prior written consent of the Company.

### *Convertible Notes*

As part of its obligations under the Exchange Agreement, the Company will issue a convertible note to Apple Tree Partners in the amount of \$1,420,000 which will accrue interest at 2.00% per annum (capitalised monthly in arrears). The convertible note is freely transferable by the holder and unsecured.

The principal and capitalised interest on the convertible note are repayable to the holder on the second anniversary of the date of issue of the convertible note. The Company may repay all (or a portion not less than \$100,000) of the convertible note at any time on 30 days written notice to holders.

The convertible note is convertible in whole or in part on fourteen days written notice, at any time, into Shares which will rank equally with all existing Shares on issue. The conversion price is \$1.00 per Share.

The conversion price of the convertible note will be adjusted in the event of a reconstruction or reorganisation of the Shares so as to ensure that no benefit is conferred on or burden assumed by the holder. In the event of a bonus issue of securities by the Company, the conversion price will be adjusted so that the convertible note will confer on the holder the right to receive the additional number of securities which the holder would have received if conversion had occurred before the date for calculating entitlements to the bonus issue.

If the convertible note is not repaid or converted before the due date, the holder of the convertible notes may demand repayment of the principal and capitalised interest in full within 30 days of written notice to the Company. If the Company does not have at least 12 months of working capital on hand at the date of receipt of the notice, then the Company's obligation to repay the principal and interest outstanding on the convertible notes will be delayed until such working capital is available. During any such period, the holder may convert the convertible notes into Shares.

## 12.6 Summary of Material Contracts

### *Underwriting and brokering agreement*

Under this agreement, dated 8 December 2004, Emerging Growth Capital Pty Limited ("**Underwriter**") has agreed to underwrite the Offer of up to approximately 60,000,000 million Shares each at the Offer Price pursuant to this Prospectus. The Underwriter will receive an underwriting commission equal to \$500,000 plus GST. The Underwriter will also receive payment of reasonable costs and expenses incurred by the Underwriter in connection with the Offer, including legal costs, and fees payable to sub-underwriters approved by the Company up to a maximum of 3% plus GST on the amount sub-underwritten.

In accordance with US securities law, Shares will not be offered, sold or delivered in the US or to, or for the account or benefit of a US person except in connection with the Private Placement.

The Company and HeartWare, Inc. have provided a number of standard warranties including that the Company complies with the relevant conditions of the SEC no-action letter to the ASX relating to Regulation S offerings under the US Securities Act.

The Company and HeartWare, Inc. have also given a number of undertakings in respect of their

obligations under this agreement, including that:

- a) the Company will not accept any Applications where and to the extent that to do so would result in the aggregate of all Application Moneys received in connection with the Offer exceeding US\$24,950,000; and
- b) during the six month period following the Allotment Date, the Company will not issue securities or interests in the Company to any person, except as disclosed in the Prospectus or with the prior written approval of the Underwriter.

The Underwriter may terminate the agreement, and be relieved of its obligations upon the occurrence of any one of the termination events specified in the agreement (provided that in the reasonable opinion of the Underwriter, such event has or is likely to have a material adverse effect on the Offer or could give rise to a liability on the part of the Underwriter under applicable legislation and regulations) at any time prior to:

- a) a) the Company receiving valid applications for all the Shares; or
- b) the Underwriter subscribing for Shares that are the subject of any shortfall.

The termination events specified in the agreement include, inter alia:

- a) ASIC gives notices of its intention to hold a hearing, or makes an order, in relation to the Prospectus under the Corporations Act;
- b) any law or bill is introduced by the Government of Australia, or any Australian State or Territory or any policies are adopted by the Reserve Bank of Australia or any other relevant fiscal authority or the United States of America adopts legislation or a policy, which has or might in the reasonable opinion of the Underwriter have a material adverse effect on the business activities of HeartWare or the prospects of the Offer;
- c) hostilities are commenced involving, inter alia, the Commonwealth of Australia or the United States of America;
- d) any director or proposed director of the Company or HeartWare, Inc. dies or is charged with or convicted of any indictable criminal offence;
- e) the Company or HeartWare, Inc. commits or permits a breach or default in relation to any of the provisions of the agreement or the Exchange Agreement being terminated;
- f) there is a misleading or deceptive statement or omission from the Prospectus of material, or a misleading statement in the Prospectus about a future matter where there are no grounds for making the statement, and that statement or omission is materially adverse from the point of view of an investor;
- g) an insolvency event occurs with respect to the Company or HeartWare, Inc.;
- h) permission is not granted for the Company to be admitted to the Official List or is not granted within the period required by the Corporations Act;
- i) the All Ordinaries Index falls to a level that is 10% or less of the level attained at the close of trading on the business day immediately preceding the date on which the agreement is signed and maintains that level for 3 consecutive days;
- j) the Company, HeartWare, Inc. or their officers contravenes any material provision of the relevant constitution or applicable laws and regulations;



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- k) in the reasonable opinion of the Underwriter there is an adverse change in the financial or trading position of the Company or HeartWare, Inc.;
- l) the Company or HeartWare, Inc. alters its board of directors, its capital structure or its constitution (other than as disclosed in this Prospectus) without the prior written consent of the Underwriter;
- m) in the reasonable opinion of the Underwriter there is an adverse change in relation to the principal business activities of the Company or HeartWare, Inc.;
- n) a material contract is terminated, rescinded, altered or materially amended;
- o) there is an 80 basis points rise in the 90 day bank bill rate from that rate as published in the Australia Financial Review on the business day before the agreement was signed;
- p) other than as disclosed in this Prospectus or to the Underwriter, an encumbrance over all or any of the assets of the Company or HeartWare, Inc. is created or comes into existence;
- q) any information supplied by the Company or HeartWare, Inc. or any person on their respective behalf to the Underwriter or its employees or agents is or becomes false or misleading;
- r) there occurs in relation to this Prospectus, an event that in the reasonable opinion of the Underwriter requires the issue of a supplementary prospectus;
- s) any person who has consented to the inclusion of his, her or its name in this Prospectus (other than the Underwriter) withdraws that consent;
- t) there is a natural disaster in Florida, Sydney or any other location in which the Company or HeartWare, Inc. carries on business and which in the reasonable opinion of the Underwriter is likely to have a material adverse affect on the operation of the Company or HeartWare, Inc.;
- u) without the prior written approval of the Underwriter, a public statement in relation to this Prospectus or the Offer is made by the Company, HeartWare, Inc. or any of their officers, employees, agents or advisers.

Subject to certain limitations, the Company and HeartWare, Inc. have agreed to jointly and severally indemnify the Underwriter, each related body corporate of the Underwriter and each of their respective officers, employees, agents and advisors (each an “**Indemnified Party**”) against all losses, claims, actions, liabilities and expenses (each a “**Loss**”) in respect of:

- (a) the Offer or the Prospectus;
- (b) a breach of any provisions of the agreement.

### *Exchange Agreement*

On 13 December 2004, the Company entered into a Securities Exchange Agreement (“**Exchange Agreement**”) with Apple Tree Partners and Anthony Low-Ber, individually and for Weiss, Peck and Gallagher as trustee, Edward Nersessian and Mary Luallen, each individually and as joint tenants with right of survivorship, and Garret G. Thunen and Carol Thunen, each individually and as joint tenants with right of survivorship (the “**Selling Stockholders**”).

Under the Exchange Agreement and, subject to the conditions noted below, the Company has agreed to acquire from the Selling Stockholders Shares of Series B Preferred Stock and promissory notes (collectively, the “**Securities**”) for a purchase consideration comprising 88 million Shares



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("Buyer Shares") and the convertible note summarised in **Section 12.5 ("Buyer Note")**. The Buyer Shares and Buyer Note will be issued immediately prior to the Offer and the US Private Placement and will, on issue, constitute approximately 58.79% of the issued capital of the Company based on the Lower Target Subscription and completion of the Offer and the US Private Placement, or approximately 55.07% based on the Upper Target Subscription and completion of the Offer and the US Private Placement.

HeartWare, Inc. has provided to the Company usual warranties in respect of the Buyer Shares and the Buyer Note including, *inter alia*, as to title to assets, financial statements, compliance with applicable laws, adequate insurance and necessary licences, permits and approvals.

The Exchange Agreement contains a number of conditions precedent to completion of the exchange and to the issue of the Buyer Shares to the Selling Stockholders and the Buyer Note to Apple Tree Partners. The Company expects that immediately prior to the Offer, the only material conditions that will remain outstanding will comprise:

- successful completion of the capital raising under this Prospectus and the US Private Placement;
- approval is pending for listing on the ASX of the Buyer Shares; and
- receipt of Foreign Investment Review Board (**FIRB**) approval or a change to the *Foreign Acquisitions and Takeovers Act 1975* (Cth) such that FIRB approval is no longer required.

### *Security Agreement*

On 23 October 2003 and as amended on 9 March 2004, HeartWare, Inc. granted to Apple Tree Partners a security interest in all of the assets of HeartWare, Inc. to secure HeartWare, Inc.'s obligations under the notes issued by HeartWare, Inc. to Apple Tree Partners referred to in **Section 9.2**. The security interest terminates on the conversion of the notes into Series B stock in HeartWare, Inc. which is planned to occur on or before the completion of the Exchange Agreement summarised in this **Section 12.6**.

### *Chief Executive Officer Contract*

The Company has entered into an Executive Services Agreement relating to the appointment of Mr Stuart McConchie as the Chief Executive Officer of the Company. Under this agreement, Mr McConchie is entitled to the following:

- a total remuneration package of \$470,000 per annum (inclusive of superannuation contributions); and
- options under the Employee Share Option Plan which provides that he will receive options equal to 3% of the issued capital on listing. Specifically, at the Upper Target Subscription Amount, this is estimated to be 1,185,015, 1,185,015, 1,185,015 and 1,185,015 options exercisable at \$0.60, \$0.75, \$1.00 and \$1.50 on the first, second, third and fourth anniversaries after listing of the Shares on the ASX, respectively, subject to Mr McConchie's continued employment with the Company on the relevant vesting date. A summary of the terms of the Employee Share Option Plan is set out in **Section 12.5**.

In addition to his remuneration package, Mr McConchie is eligible to participate in the Company's performance-based bonus scheme. The amount of bonus payable to Mr McConchie (if any) will be determined by the Board in its absolute discretion having regard to the performance of the Company and Mr McConchie against key performance indicators as determined by the Board in consultation with Mr McConchie.





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Mr McConchie's remuneration package will be reviewed each year. The remuneration package will not be reduced without the consent of Mr McConchie unless the Board decides to reduce the remuneration of all senior executives of the Company, in which case, Mr McConchie's remuneration will be reduced by the same percentage as the percentage reductions applied to the remuneration of the other senior executives of the Company.

After 2 years service, either the Company or Mr McConchie may at anytime terminate this agreement with 6 months notice.

The Company may at anytime terminate Mr McConchie's employment for any reason on 6 months notice (or payment in lieu), or immediately if, inter alia, Mr McConchie:

- a) commits a serious or persistent breach of this agreement;
- b) is convicted of any offence involving fraud or dishonesty or any other serious offence which is punishable by imprisonment;
- c) is bankrupt, declared bankrupt or enters into any arrangement with his creditors generally;
- d) is precluded from taking part in the management of a corporation by the provisions of the Corporations Act;
- e) is incapacitated by physical or mental illness, accident or other circumstances beyond Mr McConchie's control; and
- f) Mr McConchie may terminate on 30 days notice his employment at anytime if there is a substantial downgrading of his position with the Company.

If the Company terminates Mr McConchie's employment other than by way of summary dismissal or if Mr McConchie terminates his employment because of a substantial downgrading of his position with the Company, Mr McConchie will be entitled to a termination payment the maximum amount of which is equal to his annual remuneration package payable to him immediately prior to the termination of his employment, payable by monthly instalments subject to certain conditions set out in this agreement.

### *Chief Technical Officer Contract*

HeartWare, Inc. has entered into an at will Employment Agreement dated 21 November 2004 relating to the appointment of Mr Jeff LaRose as Chief Technical Officer of HeartWare, Inc. Under this Agreement, Mr LaRose is entitled to a base salary on listing of the Company of US\$175,000 per annum and participation in the Company's employee share option plan.

He is eligible to participate in HeartWare, Inc.'s performance-based bonus scheme as determined by the board of HeartWare, Inc.

### *Contracts with Minnetronix Inc.*

On 20 January 2004, HeartWare, Inc. entered into a System Development Proposal with Minnetronix Inc. ("Minnetronix"). The proposal provides that Minnetronix will serve as HeartWare, Inc.'s design partner focusing on control software to accompany the heart device and will assist with commercialization of the HeartWare, Inc. products. The term of the agreement will continue until the completion of Phase II, projected to be 28 December 2004. The estimate of fees for Phases II and III of this project is US\$1,640,730. HeartWare, Inc. may terminate the agreement at anytime with 30 days notice.



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On 3 November 2004, HeartWare, Inc. entered into a Technology Investigation Proposal with Minnetronix. The proposal provides that Minnetronix will serve as HeartWare, Inc.'s design partner focusing on development and commercialisation of an implantable rotary pump system. The project is scheduled to be completed on 1 February 2005. The Proposal imposed a cap on labor costs of US\$25,000 for the project.

### *Florida Lease*

HeartWare Inc leases its Florida production facility under a lease expiring on 30 April 2005. HeartWare Inc is in negotiations with the lessor for a new lease term and the Company is confident that a new lease will be entered into on terms not materially different than the current terms.

### *Copies of material contracts*

Copies of the above material contracts may be inspected at the registered office of the Company during normal business hours by appointment with the Company Secretary.

## 12.7 Other Disclosure Items

### *Agreement with former CEO*

The Company assumed liabilities resulting from a purchase of the business that previously held the Company's technology. These liabilities included a severance package with a former CEO, Dr Robert Fine. Details of the severance arrangement are:

- US\$550,000 in monthly instalments of US\$15,000, with certain milestone based accelerations. At 30 September 2004, US\$340,000 remained outstanding;
- A milestone payment of US\$750,000 when the first circulatory assist device is approved for sale in Europe, provided that the Company has a least US\$15,000,000 in cash on hand;
- A milestone payment of US\$1,250,000 when the first circulatory assist device is approved for sale in the US, provided that the Company has at least US\$25,000,000 in cash on hand;
- A special payment of up to US\$500,000 upon the sale of HeartWare, Inc. if such sale generated proceeds in excess of the aggregate liquidation preferences of all of HeartWare, Inc.'s then outstanding preferred stock; and
- A warrant (or options) for 3% of HeartWare, Inc. on a fully diluted based, as described in **Section 12.5**

## 12.8 HeartWare, Inc. Retention and Equity Rights Plan

HeartWare, Inc. adopted a Retention and Equity Rights Plan ("**Bonus Plan**") on 27 February 2004. Participants in the Bonus Plan are eligible for a bonus to be paid upon the effectiveness of a company sale (defined therein to include a sale of substantially all the assets of HeartWare, Inc.). The amount of the bonuses paid to individual participants will vary according to the percentage of the equity rights pool (defined therein) that each participant was assigned upon joining the Bonus Plan. HeartWare, Inc. intends to terminate the Bonus Plan and replace it with the HeartWare Limited Employee Share Option Plan described in **Section 12.5**.

## 12.9 No Litigation

The Company is not involved in any material legal or arbitration proceedings nor does the Company believe that there are any such proceedings pending or threatened against it other than the threat of litigation by Ventracor Limited disclosed in **Section 11.2**, which the Company believes is frivolous in nature and which the Company will vigorously defend if legal proceedings are instigated by Ventracor Limited.

## 12.10 Expenses of the Offer

The total expenses (exclusive of GST) of the Offer (including underwriting, advisory, legal, accounting, tax, listing and administrative fees, as well as printing and other expenses) are currently estimated to be approximately \$2,727,000 at the Upper Target Subscription which is based on an exchange rate of A\$1.00 = US\$0.7129.

## 12.11 Interests of Directors

### *Disclosure*

Except as disclosed in this **Section 12.11**, no Director or proposed Director has, or has had during the last two years before lodgement of this Prospectus, any interest in formation or promotion of the Company or the Offer, or in any property acquired or proposed to be acquired by the Company in connection with its formation or promotion or the Offer; nor has been paid or agreed to be paid, nor has been given or agreed to be given any benefit, either to induce him or her to become, or to qualify him or her, as a director, or for services provided by him or her in connection with the promotion or formation of the Company, or the Offer.

### *Directors' Shares Interest*

Except as disclosed in this **Section 12.11**, no Director as at the date of this Prospectus has an interest in any Shares. However, Directors may acquire Shares pursuant to the Offer.

### *Director's Option Interests*

The current Directors and their respective holdings of options are as follows:

| Director             | Vest after 1 Year  | Vest after 2 Years | Vest after 3 Years | Vest after 4 Years | Total            |
|----------------------|--------------------|--------------------|--------------------|--------------------|------------------|
| Robert Thomas        | 200,000<br>197,503 | 200,000<br>197,503 | 100,000<br>197,503 | 197,503            | 1,290,010        |
| Dr Christine Bennett | 100,000            | 100,000            | 50,000             |                    | 250,000          |
| Dr Denis Wade AM     | 100,000            | 100,000            | 50,000             |                    | 250,000          |
| Stuart McConchie     | 1,185,015          | 1,185,015          | 1,185,015          | 1,185,015          | 4,740,060        |
| <b>Total</b>         | <b>1,782,518</b>   | <b>1,782,518</b>   | <b>1,582,518</b>   | <b>1,382,518</b>   | <b>6,530,070</b> |

<sup>1</sup> Mr Thomas has been granted 0.5% of ESOP options which is summarised in **Section 12.5**. This number of options assumes the Upper Target Subscription Amount

<sup>2</sup> Mr McConchie has been granted 3% of ESOP options which is summarised in **Section 12.5**. This number of options assumes the Upper Target Subscription Amount.

In addition, Dr Harrison, is a related party to Apple Tree Partners which will on completion of the Offer hold 87,005,221 Shares in the Company, \$1,420,000 of convertible notes, and options over two thirds of the Fine Options.



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### *Directors' Fees*

The Non-Executive Chairman, Mr Robert Thomas, is entitled to a fee of A\$120,000 per annum and the other two Non-Executive Directors, Dr Christine Bennett and Dr Denis Wade AM, are each entitled to receive fees of A\$60,000 per annum. These fees exclude superannuation which will be paid in addition to the directors fees.

The remuneration of the Managing Director is set out in **Section 12.6**.

### *Directors' Indemnity, Access and Insurance*

The Company has entered into a Deed of Indemnity, Access and Insurance with each of the Directors under which the Company agrees, to the extent permitted by law, to provide certain indemnities to each of those persons, and to provide certain rights of access to books and records of the Company to those persons. The Company may also obtain directors' and officers' insurance for those persons.

## 12.12 Restrictions on US ownership under US Securities Laws

### *Regulation S*

The US Securities Act governs offers and sales of securities of US companies, and companies organised under the laws of other countries where more than 50% of the outstanding voting securities of such a company are held of record by residents of the US and where certain conditions are met (which companies are considered to be US domestic issuers), including:

- a majority of executive officers or directors are US citizens or residents;
- more than 50% of its assets are in the US; or
- its business is administered principally in the US.

As the Company will be considered a US domestic issuer for the purposes of Regulation S, Regulation S will apply to an offer of Shares of the Company.

The Shares issued in respect of the Offer have not been and will not be registered under the US Securities Act, but rather are being issued in reliance on an exemption from registration contained in Regulation S under the US Securities Act for offers and sales made outside of the US.

Because of the restrictions imposed by Regulation S, the Shares offered under the Offer may not be, and are not being offered, sold or delivered in the US or to, or for the account or benefit of, any US Person (see below) and may not be acquired by any US Person in any resale transactions for the foreseeable future.

In addition, hedging transactions with regard to the Shares may only be conducted in accordance with the US Securities Act.

The above restrictions preclude purchasers of Shares offered under the Offer from reselling the Shares in the US or to a US Person for the foreseeable future, except in very limited circumstances after the expiration of a restricted period. Thus, the market for Shares is likely to be limited to the ASX.



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### *January 2000 No-action letter*

In January 2000, the SEC issued a no-action letter to ASX with regard to initial public offerings of US private companies on ASX. The no-action letter describes certain limitations and controls to be implemented in connection with an offering on the ASX by a US domestic issuer without registering the offered Shares under the US Securities Act. The no-action letter requires that the purchasers of Shares pursuant to the Offer, and any persons who purchase Shares in the secondary market, have to make representations about their non-US status. The no-action letter is based on certain assumptions and also requires that HeartWare, ASX, the CUSIP Bureau, the Underwriter and the ASX Participating Organisations (as defined below) take certain actions in order to comply with the requirements set forth in the no-action letter.

### *Purchaser representations regarding non-US status*

Each purchaser of Shares offered under this Prospectus will be deemed to have represented and agreed as follows:

- The purchaser is not a US Person and is not acting for the account or benefit of a US Person. A US Person means, among other things and subject to certain exceptions:
  - any natural person resident in the US;
  - any partnership, corporation or other entity organised or incorporated under the laws of the US;
  - any estate of which any executor or administrator is a US person;
  - any trust of which any trustee is a US person;
  - any agency or branch of a foreign entity located in the US;
  - any non-discretionary account or similar (other than a trust or estate) held by a dealer or other fiduciary for the benefit or account of a US person;
  - any discretionary account or similar account (other than a trust or estate) held by a dealer or other fiduciary organised, incorporated or (if an individual) resident in the US; or
  - any partnership or corporation that is organised or incorporated in a foreign jurisdiction by a US Person principally for the purpose of investing in securities not registered under the US Securities Act unless it is owned by accredited investors (as defined in the US Securities Act who are not natural persons, trusts or estates).
- The purchaser understands and agrees that, if in the future it decides to resell, pledge or otherwise transfer any Shares, it will do so only:
  - outside the US in an offshore transaction in compliance with Rule 903 or Rule 904 under the US Securities Act;
  - pursuant to an effective registration statement under the US Securities Act; or
  - pursuant to an available exemption from the registration requirements of the US Securities Act, and in each case in accordance with all applicable securities laws.
- The purchaser agrees not to engage in hedging transactions with regard to Shares unless in compliance with the US Securities Act.



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- The purchaser acknowledges that the Company and the Underwriter and others will rely upon the truth and accuracy of these acknowledgments, representations and agreements and agree that if any such acknowledgments, representations or warranties deemed to have been made by virtue of its purchase of Shares are no longer accurate, it shall promptly notify the Company and the Underwriter.

### *Representations of purchasers of Shares in the secondary market*

The no-action letter requires that purchasers of Shares in the secondary market make similar certifications and agreements to the ones that the purchasers make in the Offer regarding their status as non-US Persons.

### *Requirements of ASX and CUSIP Bureau*

The no-action letter requires that the ASX and CUSIP Bureau take certain actions in order to comply with the provisions of the no-action letter:

- The Shares will be classified as Foreign Ownership Restriction (“FOR”) securities under the ASTC Settlement Rules, and will be identified on trading screens as being on the FOR list. For this purpose, ‘Foreign Person’ will be defined as a ‘US Person’, and the permitted foreign ownership level will be zero. As a result, no US Person may apply for Shares under the Offer. If you have a CHESS Holder Identification Number (“HIN”) designated as ‘Foreign’, you may not subscribe for Shares under the Offer. If for any reason Shares are purchased by a US Person, the Shares will be divested under the ASTC Settlement Rules.
- ASX will publish widely an explanation of the restricted stock identifier beginning a reasonable period prior to the initial quotation of the Shares and continually thereafter.
- The Shares will be identified in the records maintained by the CUSIP Bureau such as the International Securities Identification Directory, which publishes CUSIP and ISIN numbers, as restricted under the US Securities Act, so that participants in book entry clearance facilities and others that trade the Shares will have notice that transfers of the Shares to US purchasers are restricted and must qualify under an appropriate exemption.
- US entities may not participate in the ASX market, either as brokers or as market-makers.
- No ASX trading screens may be placed in the US.
- Whilst the ASX and ASTC will maintain these procedures and systems, neither the ASX nor ASTC is responsible for monitoring compliance with SEC requirements or US law nor is the ASX or ASTC responsible to third parties for any misfeasance by HeartWare in relation to those procedures. If HeartWare breaches US law, neither the ASX nor ASTC is responsible for those breaches.

### *Requirements of the Underwriter and ASX Participating Organisations*

The no action letter requires that the Underwriter and ASX Participating Organisations (brokers that are members of the ASX) take certain actions in order to comply with the provisions of the no-action letter:

- Whether in the Offer or in secondary trading, neither the Underwriter nor any other ASX Participating Organisation may execute a transaction on ASX in Regulation S securities if that broker knows that the purchaser is a US Person or is acting for the account or benefit of a US Person.



## 12 Additional Information

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- In connection with any purchase of Shares, whether in the Offer or in secondary trading, the Underwriter and any other ASX Participating Organisations must make all reasonable efforts to ascertain whether a purchaser is a US Person or is acting for the account or benefit of a US Person, and implement measures designed to assure reasonable compliance with this requirement.
- The confirmation sent to each purchaser of Shares in either the Offer or in the secondary market trading will include a notice that the Shares are subject to the restrictions of Regulation S.
- Any information provided by the Underwriter to publishers of publicly available databases, such as Bloomberg and Reuters, about the term of the issuance of the Shares must include a statement that the Shares have not been registered under the US Securities Act and are subject to restrictions under Regulation S.

### *Legending Requirements*

Global securities, certificates into which global securities may be subdivided and any physical certificate representing Shares issued prior to the end of the restricted period will bear certain restrictive legends required under Regulation S and other pertinent provisions of the US Securities Act and the regulations promulgated under the US Securities Act.

### *Requirements of HeartWare*

The no-action letter also requires that the issuer of the Shares take certain actions in order to comply with the provisions of the no-action letter:

- HeartWare undertakes to provide notification of the Regulation S status of its Shares in shareholder communications such as annual reports, periodic interim reports, and notices of shareholder meeting.
- The Constitution must provide that the issuer will refuse to register any transfer of the Shares not made:
  - in accordance with the provisions of Regulation S (Rule 901 through Rule 905, and preliminary notes);
  - pursuant to registration under the US Securities Act; or
  - pursuant to an available exemption from registration.
- During the distribution compliance period, HeartWare undertakes that any information provided by HeartWare to publishers of publicly available databases, such as Bloomberg and Reuters, about the term of the issuance of the Shares must include a statement that the Shares have not been registered under the US Securities Act and are subject to restrictions under Regulation S.

### *Concurrent Regulation D Private Placement*

Concurrent with the Offer, the Company is offering up to 10,000,000 Shares at an issue price of \$0.50 per Share to raise up to \$5,000,000 in a separate private placement pursuant to an exemption from registration contained in Regulation D of the US Securities Act ("**US Private Placement**"). The closing of the US Private Placement is contingent on the closing of the Offer.

Apple Tree Partners, the Company's major shareholder, has agreed that to the extent that the Company is not able to raise the entire \$5,000,000 in the US Private Placement, Apple Tree Partners



## 12 Additional Information

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will purchase in the US Private Placement that number of Shares equal to 10,000,000 minus the number of Shares subscribed for by eligible investors in the US Private Placement. Seth Harrison MD, one of the Directors, is the Managing General Partner of Apple Tree Partners.

### 12.13 Interests of Named Persons and the Underwriter

Other than as set out below, no person named in this Prospectus as providing professional or advisory services in connection with the preparation or distribution of this Prospectus or any firm in which any such person is a partner has had at any time during the two years preceding the date of this Prospectus, any interest in the formation of or promotion of, or in any property acquired or proposed to be acquired by, the Company, or the Offer; nor has been paid or agreed to be paid any amount or given or agreed to be given any other benefit for services rendered by them in connection with the formation or promotion of the Company or the Offer.

The Company has engaged the following professional advisers:

- Grant Thornton LLP has acted as auditors to HeartWare, Inc. and their related party, Grant Thornton Corporate (NSW) Pty Limited as independent accountants to the Company who have prepared the Independent Accountant's Report in **Section 10**. The Company has paid or agreed to pay, approximately \$58,000 and US\$37,500 for these services.
- Corrs Chambers Westgarth has acted as Australian legal adviser to the Company in relation to the Offer, has performed work in relation to due diligence enquiries and advised the Company generally in relation to the Offer. The Company has paid or agreed to pay approximately \$250,000 for these services, to the date of this Prospectus. Further amounts may be paid to Corrs Chambers Westgarth in accordance with its usual time-based charge out rates.
- Sullivan & Worcester has acted as US legal adviser to the Company and HeartWare in relation to the Offer, has performed work in relation to the due diligence enquiries and advised the Company generally in relation to the US securities law aspects of the Offer. The Company has paid or agreed to pay US\$70,000 plus up to US\$20,000 for the cost of Delaware legal counsel.
- Seyfarth Shaw LLP has acted as patent attorneys to the Company and prepared the Report on Patents and Patent Applications in Section 6. The Company has paid or agreed to pay, approximately US\$5,000 for these services.
- Inteq Limited has acted as corporate adviser to the Company. The Company has paid or agreed to pay fees of approximately \$250,000 for these services plus GST and reasonable disbursements. In addition, Inteq is entitled to a fee on completion of the Offer, which equates to \$1.15 million from which the \$250,000 will be deducted. The Company has agreed to issue to Inteq Limited 500,000 incentive options on the terms set out in **Section 12.5**.
- Emerging Growth Capital Pty Limited has acted as the Underwriter to the Offer. The Company has paid or agreed to pay an underwriting fee of \$500,000 for these services plus an agreed reimbursement of disbursements. The Company will also pay the Underwriter the fees payable to sub-underwriters approved by the Company up to a maximum of 3% plus GST on the amount sub-underwritten. The terms of the underwriting and these fees are more fully described in **Section 12.6**.
- Aoris Nova Pty Ltd has acted as technical expert to the Company and prepared the Independent Expert's Report in **Section 8**. The Company has paid or agreed to pay \$35,000 for these services.





## 12 Additional Information

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All professional fees referred to above are exclusive of GST and agreed disbursements.

The Company has also agreed to reimburse Apple Tree Partners for legal expenses up to US\$70,000 in accordance with the terms of the Exchange Agreement.

### 12.14 Consents to the Inclusion of Information

The following persons have given and have not, before the issue of this Prospectus, withdrawn their written consent to the issue of this Prospectus with the inclusion of the following information in the form and context in which it is included:

- Emerging Growth Capital Pty Limited to being named as Underwriter and broker to the Offer
- Inteq Limited to being named as corporate advisers of the Company
- Grant Thornton LLP to being named as auditors of the Company
- Grant Thornton Corporate (NSW) Pty Ltd to being named as independent accountants to the Company
- Corrs Chambers Westgarth to being named as Australian lawyers to the Company
- Sullivan & Worcester LLP to being named US lawyers to the Company
- Seyfarth Shaw LLP to being named as patent attorneys to the Company
- Registries Limited to being named as the Share Registry

### 12.15 Responsibility Statements

Each person named in Section 12.14 of this Prospectus:

- has not authorised or caused the issue of this Prospectus
- does not make, or purport to make, any statement in this Prospectus to the maximum extent permitted by law, expressly disclaims and takes no responsibility for any part of this Prospectus, other than consenting to the inclusion as detailed in Section 12.14.

### 12.16 Governing Law

This Prospectus and the contracts that arise from the acceptance of the Applications are governed by the applicable laws of the State of New South Wales, Australia and each Applicant submits to the jurisdiction of the courts of State of New South Wales.



## 13 Directors' Authorisation

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Each of the Directors of the Company has consented to the lodgement of this Prospectus with ASIC.

17 December 2004

A handwritten signature in black ink, appearing to read 'R. Thomas', with a long horizontal flourish extending to the right.

**Robert Thomas**  
Chairman



## 14 Glossary of Defined Terms

In this Prospectus, the following terms and abbreviations have the following meanings, unless the context otherwise requires:

|                         |   |
|-------------------------|---|
| “\$”                    | Australian dollar, the lawful currency of Australia   |
| “Advisory Board”        | HeartWare’s Advisory Board, as summarised in <b>Section 7.2</b>   |
| “AEDT”                  | Australian Eastern Daylight savings Time  |
| “AGAAP”                 | Australian Generally Accepted Accounting Principles   |
| “AHF”                   | Artificial Heart Fund, a charitable organisation based at Oxford, United Kingdom  |
| “Allotment Date”        | the date of allotment of Shares under the Offer   |
| “Apple Tree Partners”   | Apple Tree Partners I, L.P.   |
| “Applicant”             | an applicant for Shares who duly completes an Application Form and pays the applicable Application Money  |
| “Application Form”      | a valid application to subscribe for or acquire a specified number of Shares under this Offer   |
| “Application Money”     | money submitted by Applicants in respect of their Applications.   |
| “Application Period”    | the period between the opening and closing date of this Prospectus  |
| “Application”           | a valid application to subscribe for or acquire a specified number of Shares under this Offer   |
| “ASIC”                  | the Australian Securities and Investments Commission  |
| “ASTC”                  | ASX Settlement and Transfer Corporation Pty Limited (ABN 49 008 504 532)  |
| “ASTC Settlement Rules” | the Business Rules of the Securities Clearing House ASTC regarding the operation of CHESS   |
| “ASX”                   | Australian Stock Exchange Limited (ABN 98 008 624 691)  |
| “Board” or “Directors”  | the directors of the Company  |
| “Bridge to transplant”  | the use of a circulatory assist device as a temporary measure to sustain the patient’s heart until a donor heart is available   |
| “CE mark”               | the approval to sell medical devices in the EU, that comply with the requirements of the Medical Device Directive and the Active Implantable Devices Directive  |
| “CEO”                   | Chief Executive Officer   |
| “CHESS”                 | Clearing House Electronic Sub-register System   |
| “CHF”                   | congestive heart failure, a disease of the heart  |
| “Closing Date”          | the date on which the Offer closes, being 19 January 2005 or such other earlier or later date determined by the Directors in consultation with the Underwriter  |
| “Constitution”          | the Constitution of the Company   |
| “Corporate Adviser”     | Inteq Limited (ABN 16 055 971 232)  |
| “Corporations Act”      | the Corporations Act 2001 (Cth)   |
| “Destination therapy”   | the permanent use of a circulatory assist device for patients suffering from end stage heart failure who are not eligible for transplantation   |
| “EU”                    | the European Union, an economic and political union established in 1993 by members of the European Community, which now has 25 member countries   |
| “Exchange Agreement”    | the agreement whereby the Company will acquire the Series B stock in HeartWare, Inc. upon completion of the listing on the ASX, as summarised in <b>Section 12.6</b>  |
| “Exposure Period”       | the period of seven days from Date (being the date this Prospectus was lodged with ASIC) unless the period is extended by ASIC by up to a further seven days in which case it means the extended period                       |
| “FDA”                   | the US Food and Drug Administration   |
| “HeartWare, Inc.”       | a Delaware corporation which currently owns the technology to be operated by HeartWare, the voting Shares in which will be acquired by the Company pursuant to the Exchange Agreement, as summarised in <b>Section 12.6</b> . |



## 14 Glossary of Defined Terms

|                              |   |
|------------------------------|---|
| "HeartWare" or "the Company" | HeartWare Limited ACN 111 970 257   |
| "HVAD"                       | HeartWare's first product the Heart Ventricular Assist Device   |
| "IABPs"                      | intra-aortic balloon pumps  |
| "Investor"                   | a person considering an investment in Shares  |
| "IPO"                        | Initial Public Offering   |
| "Listing Rules"              | the official listing rules of the ASX   |
| "Lower Target Subscription"  | Approximately 60,000,000 Shares to raise \$30 million under the Offer and the US Private Placement  |
| "LVAD"                       | left ventricle assist device, used in the treatment of congestive heart failure   |
| "Material Agreements"        | those agreements and arrangements referred to and summarised in <b>Section 12.6</b>   |
| "MVAD"                       | HeartWare's Miniaturised Ventricular Assist Device  |
| "NYHA"                       | New York Heart Association which categorises heart failure into Classes I to IV as described in <b>Section 2.5</b>  |
| "Offer Price"                | the offer price of \$0.50 per Share   |
| "Offer"                      | the Offer to issue the Shares each at \$0.50, made pursuant to this Prospectus  |
| "Official List"              | the official list of ASX  |
| "Opening Date"               | 29 December 2004  |
| "PMA"                        | Pre Market Approval from the FDA, to approve a Class III medical device   |
| "Prospectus"                 | this Prospectus, dated 17 December 2004 for the issue of 60,000,000 Shares  |
| "SEC"                        | United States Securities and Exchange Commission  |
| "Share Option Plan"          | the share option plan of the Company as amended from time to time which is summarised in <b>Section 12.5</b> of this Prospectus   |
| "Share Registry"             | Registries Limited, ABN 14 003 209 836  |
| "Shareholder"                | a holder of any Shares in the Company   |
| "Shares"                     | ordinary Shares in the Company  |
| "Underwriter"                | Emerging Growth Capital Pty Limited   |
| "Underwriting Agreement"     | the Underwriting Agreement entered into between the Company and the Underwriter dated on 8 December   |
| "United States" or "US"      | United States of America  |
| "Upper Target Subscription"  | approximately 70,000,000 Shares to raise \$35 million under the Offer and US Private Placement  |
| "US Private Placement"       | a private placement of up to approximately 10,000,000 Shares pursuant to an exemption from registration contained in Regulation D of the US Securities Act, as summarised in <b>Section 12.12</b> |
| "US Securities Act"          | United States Securities Act of 1933, as amended, and the rules promulgated thereunder  |
| "US\$"                       | United States dollar  |
| "Use of Funds"               | the Company's proposed use of the proceeds of the Offer as set out in <b>Section 1.3</b>  |
| "USGAAP"                     | US Generally Accepted Accounting Practices  |

References in this Prospectus to Sections are to Sections of this Prospectus. References in this Prospectus to currency are, unless stated otherwise, to the currency of Australia.

## Corporate Directory

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### *Board of Directors*

Robert Thomas, Non-Executive Chairman  
Seth Harrison, MD, Non-Executive Deputy Chairman  
Stuart McConchie, CEO  
Christine Bennett, MB, Non-Executive Director  
Denis Wade AM, MB, D.Phil, Non-Executive Director.

### *Advisory Board*

O. Howard 'Bud' Frazier, MD (Chairman)  
Steven Boyce, MD  
Laman Gray Jr., MD  
Stephen Westaby, MD  
Georg Wieselthaler, MD

### *Chief Executive Officer*

Stuart McConchie

### *Company Secretary*

Stuart McConchie

### *Registered Address*

Level 1  
1 Bligh Street  
SYDNEY NSW 2000  
AUSTRALIA

### *US Office*

3351 Executive Way  
Miramar  
MIAMI FLORIDA 33025-3935  
UNITED STATES OF AMERICA  
AUSTRALIA

### *Corporate Adviser*

Inteq Limited  
AFSL 237244  
Level 1  
1 Bligh Street  
SYDNEY NSW 2000  
AUSTRALIA

### *Auditors*

Grant Thornton  
Level 17  
383 Kent Street  
SYDNEY NSW 2000  
AUSTRALIA

### *Australian Legal Adviser*

Corrs Chambers Westgarth  
Governor Phillip Tower  
1 Farrer Place  
SYDNEY NSW 2000  
AUSTRALIA

### *US Legal Adviser*

Sullivan & Worcester  
One Post Office Square  
Boston, MA 02109  
UNITED STATES OF AMERICA

### *Patent Attorneys*

Seyfarth Shaw LLP  
Suite 4200  
55 East Monroe Street  
CHICAGO ILLINOIS 60603  
UNITED STATES OF AMERICA

### *Share Registry*

Registries Limited  
Level 2  
28 Margaret Street  
SYDNEY NSW 2000  
AUSTRALIA

### *Underwriters*

Emerging Growth Capital Pty Limited  
Level 3  
1 Castlereagh Street  
SYDNEY NSW 2000  
AUSTRALIA

## Supplementary Prospectus

This is a supplementary prospectus dated 24 December 2004 ("**Supplementary Prospectus**") and is intended to be read in conjunction with the prospectus issued by HeartWare Limited ("**HeartWare**") dated 17 December 2004 in relation to an offer of up to approximately 60,000,000 ordinary shares in HeartWare at a price of \$0.50 per share ("**Prospectus**").

This Supplementary Prospectus was lodged with ASIC on 24 December 2004. No previous supplementary documents have been lodged with ASIC in relation to the Prospectus. Neither ASIC or the ASX takes any responsibility for the contents of this Supplementary Prospectus.

Terms used in this Supplementary Prospectus have the same meaning as defined in the Prospectus unless otherwise indicated.

### *Ventracor patent litigation*

As disclosed in the Prospectus, and in particular in **Section 11.2**, one of HeartWare, Inc.'s competitors, Ventracor Limited ("**Ventracor**"), had written to HeartWare, Inc. alleging patent infringements by HeartWare, Inc.. After the Prospectus was lodged on 17 December 2004, Ventracor commenced legal action against HeartWare, Inc. in the United States District Court for the Southern District of Florida in relation to two of Ventracor's US patents. The suit seeks an award for damages including treble damages for wilful infringements, interest and attorney's fees and a permanent injunction.

The Board of HeartWare believes that the legal action by Ventracor is opportunistic and designed to disrupt the Company's capital raising efforts. Moreover, the Board believes that the legal action has no validity whatsoever and is frivolous in nature.

The Company intends to vigorously defend the legal action brought by Ventracor, including the seeking of appropriate damages.

Having taken into account the potential costs of defending the Ventracor legal action, the Directors reconfirm their statement on page 15 of the Prospectus that following completion of the Offer, the Directors believe that the Company will have sufficient working capital to conduct its business as outlined in the Prospectus for at least the next 18 months.

### *Consent*

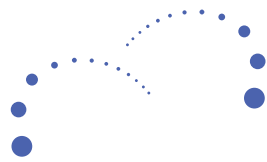
Each director of HeartWare has consented to the lodgement of this Supplementary Prospectus with ASIC and has not withdrawn that consent.



**Rob Thomas**  
Director  
HeartWare Limited

24 December 2004

PIN CHEQUE(S) HERE



# HeartWare Application Form

Broker Code

Advisor Code

Fill out this Application Form if you want to apply for fully-paid ordinary shares (Shares) in HeartWare Limited.

- Read the Prospectus dated 17 December 2004 and the Supplementary Prospectus dated 24 December 2004 to which this application relates.
- Follow the instructions to complete this Application Form (see reverse).
- Print clearly in capital letters using black or blue pen.

**A** Number of Shares you are applying for

x \$0.50 per share =

**B** Total amount payable

Minimum of 4,000 Shares [A\$2,000.00] to be applied for, and thereafter in multiples of 1,000 Shares [A\$500.00].

**C** Write the name(s) you wish to register the Shares in (see reverse for instructions)

Applicant 1

Name of Applicant 2 or < Account Designation >

Name of Applicant 3 or < Account Designation >

**D** Write your postal address here

Number / Street

Suburb/Town

State

Postcode

**E** CHESS participant – Holder Identification Number (HIN)

X

**F** Enter your Tax File Number(s), ABN, ACN or exemption category

Applicant #1

Applicant #2

Applicant #3

**G** Cheque payment details

Please enter details of the cheques that accompany this application

Name of drawer of cheque

Cheque No.

BSB No.

Account No.

Amount A\$

**H** Contact telephone number (daytime/work/mobile)

Email address

## IMPORTANT NOTICE

The Corporations Act prohibits any person from passing onto another person the Application Form which is attached to this Prospectus, unless the Application Form is attached to or accompanied by a complete and unaltered copy of the Prospectus. A person who gives another person access to the Application Form must at the same time give that person access to the Prospectus, and any supplementary prospectus. While the Prospectus is current, a paper copy of the Prospectus, any supplementary prospectus and the Application Form will be provided to you, at no charge, upon request by telephoning the Underwriter (Emerging Growth Capital Pty Limited) on (02) 9222 1991. Applications for Shares will only be accepted if made on an Application Form issued together with the Prospectus.

## DECLARATION

By submitting this Application form, I/We declare that I/we am/are not a US person, that I am not a resident of the United States, that I am not acquiring Shares for the benefit of a US person, that this Application is completed and lodged according to the Prospectus and the instructions on the reverse of the Application form and that all details and statements made by me/us are complete and accurate. I/We agree to be bound by the constitution of HeartWare Limited. I/We was/were given access to the Electronic Prospectus together with the Application Form. I/We represent, warrant and undertake to the Company that our subscription for the above securities will not cause the Company or me/us to violate the securities or other laws of Australia or any other jurisdiction which may be applicable to this subscription for securities in the Company.

# GUIDE TO THE APPLICATION FORM

YOU SHOULD READ THE PROSPECTUS AND THE SUPPLEMENTARY PROSPECTUS CAREFULLY BEFORE COMPLETING THIS APPLICATION FORM.

Please complete all relevant sections of the appropriate Application Form using BLOCK LETTERS. These instructions are cross-referenced to each section of the Application Form.

## Instructions

- A** If applying for Shares insert the number of Shares for which you wish to subscribe at Item A (not less than 4,000 and then in multiples of 1,000). Multiply by \$ 0.50 AUD to calculate the total for Shares and enter the \$amount at B.
- C** Write your full name. Initials are not acceptable for first names.
- D** Enter your postal address for all correspondence. All communications to you from HeartWare Limited will be mailed to the person(s) and address as shown. For joint Applicants, only one address can be entered.
- E** If you are sponsored in CHESS by a stockbroker or other CHESS participant, you may enter your CHESS HIN if you would like the allocation to be directed to your HIN.  
NB: your registration details provided must match your CHESS account exactly.
- F** Enter your Australian tax file number ("TFN") or ABN or exemption category, if you are an Australian resident. Where applicable, please enter the TFN /ABN of each joint Applicant. Collection of TFN's is authorised by taxation laws. Quotation of your TFN is not compulsory and will not affect your Application Form.
- G** Complete cheque details as requested. Make your cheque payable to HeartWare Limited - Subscription Account in Australian currency, cross it and mark it "Not Negotiable". Cheques must be made in Australian currency, and cheques must be drawn on an Australian Bank.
- H** Enter your contact details so we may contact you regarding your Application Form or Application Monies.
- I** Enter your email address so we may contact you regarding your Application Form or Application Monies or other correspondence.

## CORRECT FORMS OF REGISTRABLE TITLE

Note that ONLY legal entities can hold the Shares. The Application must be in the name of a natural person(s), companies or other legal entities acceptable to HeartWare Limited. At least one full name and surname is required for each natural person.

Examples of the correct form of registrable title are set out below.

| Type of Investor            | Correct Form of Registrable Title                  | Incorrect Form of Registrable Title |
|-----------------------------|--|-------------------------------------|
| Trusts                      | Mr John David Smith<br><J D Smith Family A/C>      | John Smith Family Trust             |
| Deceased Estates            | Mr Michael Peter Smith<br><Est Lte John Smith A/C> | John Smith (deceased)               |
| Partnerships                | Mr John David Smith & Mr Ian Lee Smith             | John Smith & Son                    |
| Clubs/Unincorporated Bodies | Mr John David Smith<br><Smith Investment A/C>      | Smith Investment Club               |
| Superannuation Funds        | John Smith Pty Limited<br><J Smith Super Fund A/C> | John Smith Superannuation Fund      |

## Lodgement

Mail your completed Application Form with cheque(s) attached to the following address:

Delivery address:

HeartWare Limited  
C/- Registries Limited  
Level 2  
28 Margaret Street  
SYDNEY NSW 2000

Mailing address:

HeartWare Limited  
C/- Registries Limited  
PO Box R67  
Royal Exchange  
SYDNEY NSW 1223

It is not necessary to sign or otherwise execute the Application Form.

If you have any questions as to how to complete the Application Form, please contact the Underwriter (Emerging Growth Capital Pty Limited) on:

Tel: (02) 9222 1991 or Registries Limited on: Tel: (02) 9290 9600



PIN CHEQUE(S) HERE



# HeartWare Application Form

Broker Code

Advisor Code

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- Read the Prospectus dated 17 December 2004 and the Supplementary Prospectus dated 24 December 2004 to which this application relates.
- Follow the instructions to complete this Application Form (see reverse).
- Print clearly in capital letters using black or blue pen.

**A** Number of Shares you are applying for

x \$0.50 per share =

**B** Total amount payable

Minimum of 4,000 Shares [A\$2,000.00] to be applied for, and thereafter in multiples of 1,000 Shares [A\$500.00].

**C** Write the name(s) you wish to register the Shares in (see reverse for instructions)

Applicant 1

Name of Applicant 2 or < Account Designation >

Name of Applicant 3 or < Account Designation >

**D** Write your postal address here

Number / Street

Suburb/Town

State

Postcode

**E** CHESS participant – Holder Identification Number (HIN)

X

**F** Enter your Tax File Number(s), ABN, ACN or exemption category

Applicant #1

Applicant #2

Applicant #3

**G** Cheque payment details

Please enter details of the cheques that accompany this application

Name of drawer of cheque

Cheque No.

BSB No.

Account No.

Amount A\$

**H** Contact telephone number (daytime/work/mobile)

Email address

## IMPORTANT NOTICE

The Corporations Act prohibits any person from passing onto another person the Application Form which is attached to this Prospectus, unless the Application Form is attached to or accompanied by a complete and unaltered copy of the Prospectus. A person who gives another person access to the Application Form must at the same time give that person access to the Prospectus, and any supplementary prospectus. While the Prospectus is current, a paper copy of the Prospectus, any supplementary prospectus and the Application Form will be provided to you, at no charge, upon request by telephoning the Underwriter (Emerging Growth Capital Pty Limited) on (02) 9222 1991. Applications for Shares will only be accepted if made on an Application Form issued together with the Prospectus.

## DECLARATION

By submitting this Application form, I/We declare that I/we am/are not a US person, that I am not a resident of the United States, that I am not acquiring Shares for the benefit of a US person, that this Application is completed and lodged according to the Prospectus and the instructions on the reverse of the Application form and that all details and statements made by me/us are complete and accurate. I/We agree to be bound by the constitution of HeartWare Limited. I/We was/were given access to the Electronic Prospectus together with the Application Form. I/We represent, warrant and undertake to the Company that our subscription for the above securities will not cause the Company or me/us to violate the securities or other laws of Australia or any other jurisdiction which may be applicable to this subscription for securities in the Company.

# GUIDE TO THE APPLICATION FORM

YOU SHOULD READ THE PROSPECTUS AND THE SUPPLEMENTARY PROSPECTUS CAREFULLY BEFORE COMPLETING THIS APPLICATION FORM.

Please complete all relevant sections of the appropriate Application Form using BLOCK LETTERS. These instructions are cross-referenced to each section of the Application Form.

## Instructions

- A** If applying for Shares insert the number of Shares for which you wish to subscribe at Item A (not less than 4,000 and then in multiples of 1,000). Multiply by \$ 0.50 AUD to calculate the total for Shares and enter the \$amount at B.
- C** Write your full name. Initials are not acceptable for first names.
- D** Enter your postal address for all correspondence. All communications to you from HeartWare Limited will be mailed to the person(s) and address as shown. For joint Applicants, only one address can be entered.
- E** If you are sponsored in CHESS by a stockbroker or other CHESS participant, you may enter your CHESS HIN if you would like the allocation to be directed to your HIN.  
NB: your registration details provided must match your CHESS account exactly.
- F** Enter your Australian tax file number ("TFN") or ABN or exemption category, if you are an Australian resident. Where applicable, please enter the TFN /ABN of each joint Applicant. Collection of TFN's is authorised by taxation laws. Quotation of your TFN is not compulsory and will not affect your Application Form.
- G** Complete cheque details as requested. Make your cheque payable to HeartWare Limited - Subscription Account in Australian currency, cross it and mark it "Not Negotiable". Cheques must be made in Australian currency, and cheques must be drawn on an Australian Bank.
- H** Enter your contact details so we may contact you regarding your Application Form or Application Monies.
- I** Enter your email address so we may contact you regarding your Application Form or Application Monies or other correspondence.

## CORRECT FORMS OF REGISTRABLE TITLE

Note that ONLY legal entities can hold the Shares. The Application must be in the name of a natural person(s), companies or other legal entities acceptable to HeartWare Limited. At least one full name and surname is required for each natural person.

Examples of the correct form of registrable title are set out below.

| Type of Investor            | Correct Form of Registrable Title                  | Incorrect Form of Registrable Title |
|-----------------------------|--|-------------------------------------|
| Trusts                      | Mr John David Smith<br><J D Smith Family A/C>      | John Smith Family Trust             |
| Deceased Estates            | Mr Michael Peter Smith<br><Est Lte John Smith A/C> | John Smith (deceased)               |
| Partnerships                | Mr John David Smith & Mr Ian Lee Smith             | John Smith & Son                    |
| Clubs/Unincorporated Bodies | Mr John David Smith<br><Smith Investment A/C>      | Smith Investment Club               |
| Superannuation Funds        | John Smith Pty Limited<br><J Smith Super Fund A/C> | John Smith Superannuation Fund      |

## Lodgement

Mail your completed Application Form with cheque(s) attached to the following address:

Delivery address:

HeartWare Limited  
C/- Registries Limited  
Level 2  
28 Margaret Street  
SYDNEY NSW 2000

Mailing address:

HeartWare Limited  
C/- Registries Limited  
PO Box R67  
Royal Exchange  
SYDNEY NSW 1223

It is not necessary to sign or otherwise execute the Application Form.

If you have any questions as to how to complete the Application Form, please contact the Underwriter (Emerging Growth Capital Pty Limited) on:

Tel: (02) 9222 1991 or Registries Limited on: Tel: (02) 9290 9600